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Medicare Program; Prospective Payment System for Hospital Outpatient Services; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Office of Inspector General

42 CFR Parts 409, 410, 411, 412, 413, 419, 489, 498, and 1003

[HCFA–1005–P]

RIN 0938–AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services

AGENCY: Health Care Financing Administration (HCFA), HHS, and Office of Inspector General (OIG), HHS.

ACTION: Proposed rule.

SUMMARY: As required by sections 4521, 4522, and 4523 of the Balanced Budget Act of 1997, this proposed rule would eliminate the formula-driven overpayment for certain outpatient hospital services, extend reductions in payment for costs of hospital outpatient services, and establish in regulations a prospective payment system for hospital outpatient services (and for Medicare Part B services furnished to inpatients who have no Part A coverage). The prospective payment system would simplify our current payment system and apply to all hospitals, including those that are excluded from the inpatient prospective payment system. The Balanced Budget Act provides for implementation of the prospective payment system effective January 1, 1999, but delays application of the system to cancer hospitals until January 1, 2000. The hospital outpatient prospective payment system would also apply to partial hospitalization services furnished by community mental health centers.

Although the statutory effective date for the outpatient prospective payment system is January 1, 1999, implementation of the new system will have to be delayed because of year 2000 systems concerns. The demands on intermediary bill processing systems and HCFA internal systems to become compliant for the year 2000 preclude making the major systems changes that are required to implement the prospective payment system. The outpatient prospective payment system will be implemented for all hospitals and community mental health centers as soon as possible after January 1, 2000, and a notice of the anticipated implementation date will be published in the **Federal Register** at least 90 days in advance.

This document also proposes new requirements for provider departments and provider-based entities. These proposed changes, as revised based on our consideration of public comments, will be effective 30 days after publication of a final rule.

This proposed rule would also implement section 9343(c) of the Omnibus Budget Reconciliation Act of 1986, which prohibits Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital, unless the services are furnished under an arrangement with the hospital. This section also authorizes the Department of Health and Human Services' Office of Inspector General to impose a civil money penalty, not to exceed $10,000, against any individual or entity who knowingly and willfully presents a bill for non-physician or other bundled services not provided directly or under such an arrangement.

This proposed rule also addresses the requirements for designating certain entities as provider-based or as a department of a hospital.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 9, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1005–P, P.O. Box 26688, Baltimore, MD 21207–0488.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1005–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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FOR FURTHER INFORMATION CONTACT:

Janet Wellham, (410) 786–4510 (for general information). Joel Schaer (OIG), (202) 619–0089 (for information concerning civil money penalties).

Kitty Ahern, (410) 786–4515 (for information related to the classification of services into ambulatory payment classification (APC) groups).

Suzanne Letsch (410) 786–4558 (for information related to volume control measures and updates).

George Morey (410) 786–4653 (for information related to the determination of provider-based status).

Janet Samen (410) 786–9161 (for information on the application of APCs to community mental health centers).

SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this document, we are providing the following table of contents.

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In addition, because there are many terms to which we refer by acronym in this rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

APC Ambulatory payment classification
APG Ambulatory patient group
ASC Ambulatory surgical center
BBA Balanced Budget Act of 1997
CAH Critical access hospital
CCI [HCFA's] Correct Coding Initiative
CCR Cost center specific cost-to-charge ratio
CHAMPUS Civilian Health and Medical Program of the Uniformed Services
CMHC Community mental health center
CMP Civil money penalty
CORF Comprehensive outpatient rehabilitation facility
CPT [Physicians'] Current Procedural Terminology, 4th Edition, 1998, copyrighted by the American Medical Association
DME Durable medical equipment
DMEPOS DME, orthotics, prosthetics, prosthetic devices, prosthetic implants and supplies
DRG Diagnosis-related group
EACH Essential access community hospital
ESRD End-stage renal disease
FDO Formula-driven overpayment
FQHC Federally qualified health center
HCPCS HCFA Common Procedure Coding System
HHA Home health agency
ICD–9–CM International Classification of Diseases, Ninth Edition, Clinical Modification
IME Indirect medical education
IOL Intraocular lens
MDC Major diagnostic category
MDH Medicare dependent hospital
MedPAC Medicare Payment Advisory Commission
MSA Metropolitan statistical area
NECMA New England County Metropolitan Area
OBRA Omnibus Budget Reconciliation Act
PPS Prospective payment system
RHC Rural health clinic
RPCH Rural primary care hospital
RRC Rural referral center
SCH Sole community hospital
SGR Sustainable growth rate
SNF Skilled nursing facility
TEFRA Tax Equity and Fiscal Responsibility Act of 1982

I. Background

As the Medicare statute was originally enacted, Medicare payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to serving Medicare beneficiaries. Later, the law was amended to limit payment to the lesser of a hospital's reasonable costs or to its customary charges. In 1983, section 601 of the Social Security Amendments of 1983 (Public Law 98–21) completely revised the cost-based payment system for most hospital inpatient services by enacting section 1886(d) of the Social

Security Act (the Act). This section provided for a prospective payment system (PPS) for acute inpatient hospital stays, effective with hospital cost reporting periods beginning on or after October 1, 1983.

Although payment for most inpatient services became subject to a PPS, hospital outpatient services continued to be paid based on hospital-specific costs, which provided little incentive for hospital efficiency for outpatient services. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the inpatient to the outpatient setting. During the 1980s, the Congress took steps to control the escalating costs of providing outpatient care. The Congress amended the statute to implement across-the-board reductions of 5.8 percent and 10 percent to the amounts otherwise payable for hospital operating costs and capital costs, respectively, and legislated a number of different payment methods for specific types of hospital outpatient services. These methods included fee schedules for clinical diagnostic laboratory tests, orthotics, prosthetics, and durable medical equipment (DME); composite rate payment for dialysis for persons with end-stage renal disease (ESRD); and payments based on blends of hospital costs and the rates paid in other ambulatory settings such as separately certified ambulatory surgical centers (ASCs) or physician offices for certain surgery, radiology, and other diagnostic procedures. Nevertheless, Medicare payment for services performed in the hospital outpatient setting remains largely cost-based.

In section 9343(f) of the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Public Law 99–509) and in section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508), the Congress required the Secretary to develop a proposal to replace the current hospital outpatient payment system with a PPS and to submit a report to the Congress on the proposed system. In OBRA 1986, the Congress paved the way for development of a PPS, under section 9343(g), by requiring fiscal intermediaries to require hospitals to report claims for services under the HCFA Common Procedure Coding System (HCPCS), and, under section 9343(c), by extending the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. HCPCS coding enabled us to determine what specific procedures and services were being billed, while the extension of the prohibition against unbundling ensured that all nonpractitioner services provided to hospital outpatients would be billed only by the hospital, not by an outside supplier, and, therefore, would be reported on hospital bills and captured in the hospital outpatient data that could be used to develop an outpatient PPS.

Section 1866(g) of the Act, as added by section 9343(c) of OBRA 1986, and amended by section 4085(i)(17) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) (Public Law 100–203), also authorizes the Department of Health and Human Services' Office of Inspector General to impose a civil money penalty (CMP), not to exceed $2,000, against any individual or entity who knowingly and willfully presents a bill in violation of an arrangement (as defined in section 1861(w)(1) of the Act).

A proposed rule to implement section 9343(c) was published in the **Federal Register** on August 5, 1988. However, those regulations were never published as a final rule, so we are including them in this regulation and will implement them as part of the final regulation implementing the hospital outpatient PPS.

The Secretary submitted a Report to Congress on March 17, 1995. The report summarized the research HCFA conducted in searching for a way to classify outpatient services for purposes of developing an outpatient PPS. The report cited Ambulatory Patient Groups (APGs), developed by 3M-Health Information Systems under a cooperative grant with HCFA, as the most promising classification system for grouping outpatient services and recommended that APG-like groups be used in designing a hospital outpatient PPS.

The report also presented a number of options that could be used, once a PPS was in place, for addressing the issue of rapidly growing beneficiary copayment. As a separate issue, we recommended that the Congress amend the provisions of the law pertaining to the blended payment methods for ASC surgery, radiology, and other diagnostic services to correct an anomaly that resulted in a less than full recognition of the amount paid by the beneficiary in calculating program payment (referred to as the formula-driven overpayment).

The Balanced Budget Act of 1997 (BBA) (Public Law 105–33), enacted on August 5, 1997, contains a number of provisions that affect Medicare payment for hospital outpatient services. The purpose of this proposed rule is to implement sections 4521, 4522, and 4523 of the BBA and section 9343(c) of OBRA 1986. Section 4521 of the BBA eliminates the formula-driven overpayment effective for services furnished on or after October 1, 1997. Because of the October 1, 1997 effective date, HCFA has already taken action to implement this provision. Section 4522 extends the current cost reductions of 5.8 percent and 10 percent (applicable to hospital outpatient operating costs and hospital capital costs, respectively) through and including December 31, 1999.

Section 4523 of the BBA amends section 1833 of the Act by adding subsection (t), which provides for implementation of a PPS for most hospitals for outpatient services furnished on or after January 1, 1999 and for cancer hospitals that are excluded from inpatient PPS for services furnished on or after January 1, 2000. We note that while the statutory effective date for the outpatient PPS is January 1, 1999, implementation of the new payment system will have to be delayed because of year 2000 systems concerns. The demands on intermediary bill processing systems and HCFA internal systems to become compliant for the year 2000 preclude making the major systems changes that are required to implement the PPS. See Section XI of this preamble (''Delay in Implementation'') for a more detailed explanation of the reasons for delay. The outpatient PPS will be implemented as soon as possible after January 1, 2000. A notice of the anticipated implementation date will be published in the **Federal Register** at least 90 days in advance. The rates that will go into effect on the implementation date will apply to all hospitals including cancer hospitals described in section 1886(d)(1)(B)(v) of the Act. The rates will be based on the rates that would have been in effect January 1, 1999 updated by the rate of increase in the hospital market basket minus one percentage point.

Section 1833(t)(1)(B) of the Act authorizes the Secretary to designate the hospital outpatient services that would be paid under the PPS. Section 1833(t)(1)(B) also requires that the outpatient PPS include inpatient services covered under Part B for beneficiaries who are entitled to Part A benefits but who have exhausted their Part A benefits or otherwise are not in a covered Part A stay. However, section 1833(t)(1)(B) specifically excludes as covered services under the outpatient PPS ambulance services and physical and occupational therapy, and speech-language pathology services, for which separate fee schedules are required by

statute. (See section 4531 of the BBA for amendments pertaining to ambulance services and section 4541 for amendments pertaining to outpatient rehabilitation services.)

Section 1833(t)(2) of the Act stipulates certain requirements for the hospital outpatient PPS. The Secretary is required to develop a classification system for covered outpatient services which may consist of groups arranged so that the services within each group are comparable clinically and with respect to the use of resources. In addition, this section specifies data requirements for establishing relative payment weights, which are to be based on median hospital costs determined by data from the most recent available cost reports; requires that the portion of the Medicare payment and the beneficiary copayment that are attributable to labor and labor-related costs be adjusted for geographic wage differences; and authorizes the establishment of other adjustments, such as outlier adjustments or adjustments for certain classes of hospitals, that are necessary to ensure equitable payments. All adjustments are required to be made in a budget neutral manner. This section concludes with the requirement that a control on unnecessary increases in the volume of covered services be established.

Section 1833(t)(3) provides for a new method of calculating beneficiary copayment. It freezes beneficiary copayment at 20 percent of the national median charges for covered services (or group of covered services) furnished during 1996 and updated to 1999 using the Secretary's estimated charge growth from 1996 to 1999. This section specifies how beneficiary deductibles are to be treated in calculating the Medicare payment and beneficiary copayment amounts and requires that rules be established regarding determination of copayment amounts for covered services that were not furnished in 1996. Further, it prescribes the formula for calculating the initial conversion factor used to determine Medicare payment amounts for 1999 and the method for updating the conversion factor in subsequent years.

Sections 1833(t)(4) and (t)(5) describe the basis for determining the Medicare payment amount and the beneficiary copayment amount for services covered under the outpatient PPS. The latter section requires the Secretary to establish a procedure whereby hospitals may voluntarily elect to reduce beneficiary copayment for some or all covered services to an amount not less than 20 percent of the Medicare payment amount. Hospitals are further allowed to advertise any such reductions of copayment amounts. Section 4451 of the BBA added section 1861(v)(1)(T) to the Act, which stipulates that bad debts will not be recognized on any copayment the hospital elects to reduce.

Section 1833(t)(6) authorizes periodic review and revision of the payment groups, relative payment weights, wage index, and conversion factor.

Section 1833(t)(7) describes how payment is to be made for ambulance services, which are specifically excluded from the outpatient PPS under section 1833(t)(1)(B).

Section 1833(t)(8) provides that the Secretary may establish a separate conversion factor for determining services furnished by cancer hospitals excluded from inpatient PPS under this PPS.

Section 1833(t)(9) prohibits administrative or judicial review of the PPS classification system, the groups, relative payment weights, adjustment factors, other adjustments, calculation of base amounts, periodic adjustments, and the establishment of a separate conversion factor for those cancer hospitals excluded from inpatient PPS.

Section 4523(d) of the BBA amends section 1833(a)(2)(B) of the Act to require payment under the PPS for some services described in section 1832(a)(2) that are currently paid on a cost basis and furnished by providers of services such as comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), hospices, and community mental health centers (CMHCs). This amendment requires that partial hospitalization services furnished by CMHCs beginning January 1, 1999 be paid under the PPS. As noted earlier, implementation of the PPS will be delayed. Implementation will occur as soon as possible after January 1, 2000.

II. Elimination of Formula-Driven Overpayment

Before enactment of section 4521 of the BBA, under the blended payment formulas for ASC procedures, radiology, and other diagnostic services, the ASC or physician fee schedule portion of the blends was calculated as if the beneficiary paid 20 percent of the ASC rate or physician fee schedule amount instead of the actual amount paid, which was 20 percent of the hospital's billed charges. Section 4521 corrects this anomaly by changing the blended calculations so that all amounts paid by the beneficiary are subtracted from the total payment in determining the amount due from the program. Effective for services furnished on or after October 1, 1997, payment for surgery, radiology, and other diagnostic services under blended payment methods will be calculated by subtracting the full amount of copayment due from the beneficiary (based on 20 percent of the hospital's billed charges).

III. Extension of Cost Reductions

Section 1861(v)(1)(S)(ii) of the Act requires that the amounts otherwise payable for hospital outpatient operating costs and capital costs be reduced by 5.8 percent and 10 percent, respectively. These reductions were scheduled to sunset at the end of fiscal year 1998, but section 4522 of the BBA extended the reductions through December 31, 1999.

IV. Prohibition Against Unbundling of Hospital Outpatient Services

A. Background

The Social Security Amendments of 1965 (Public Law 89–97), enacted on July 30, 1965, established title XVIII of the Act, which authorized the establishment of the Medicare program to pay part of the costs of health care services furnished to eligible beneficiaries. Part A of the program (Hospital Insurance) provides basic health insurance protection against the costs of inpatient or home health care. Part B of the program (Supplementary Medical Insurance) provides voluntary supplementary insurance covering most physician services and certain other items and services not covered under Part A, including hospital outpatient services.

Before the enactment of Public Law 98–21 on April 7, 1983, which established the Medicare PPS for inpatient hospital services, nonphysician services furnished to Medicare beneficiaries who were hospital patients were generally billed by the hospitals. Under certain circumstances, however, Part B of the Medicare statute permitted payments to be made to an outside supplier or another provider for certain nonphysician services otherwise covered by Medicare Part B that were furnished to a hospital patient. When payments were made under these circumstances, some nonphysician services were billed as hospital services in one hospital and billed by an outside supplier in another. The practice of billing by suppliers outside the hospital for these services has been referred to in the legislative history as the ''unbundling'' of hospital services.

Since the enactment of Public Law 98–21 and the publication of implementing regulations on September 1, 1983 (48 FR 39752), the Medicare program has required that nonphysician

services furnished to hospital inpatients be covered and paid for under Medicare as hospital services. This practice of covering nonphysician services furnished to hospital inpatients by an outside supplier as hospital services is referred to as ''bundling.'' Under the PPS for inpatient hospital services, a single predetermined payment is made for a case based on the diagnosis-related group (DRG) to which the case is assigned. Bundling ensures that the DRG payments to all hospitals cover a comparable ''bundle'' of services related to the hospital stay.

Specifically, Public Law 98–21 added section 1862(a)(14) to the Act to prohibit payment for services (other than physician services) furnished to an inpatient of a hospital by an entity other than the hospital, unless the services are furnished under an arrangement (as defined in section 1861(w)(1) of the Act). (Section 1861(w)(1) of the Act specifies that the term ''arrangements'' is limited to arrangements under which receipt of payment by the hospital or other provider for Medicare-covered services to an individual discharges the liability of the individual or any other person to pay for the services.) Public Law 98–21 also added section 1866(a)(1)(H) to the Act to provide that a hospital is eligible to participate in the Medicare program only if the hospital agrees to furnish to inpatients either directly or under an arrangement all Medicare-covered items and services, other than physician services.

Regardless of whether the hospital furnishes the services directly or arranges for furnishing the services, the hospital assumes financial responsibility for the services. The Medicare program makes payment only to hospitals and not to other providers or suppliers that furnish inpatient services on behalf of the hospitals.

In Public Law 98–21, the Congress addressed only nonphysician services furnished to Medicare beneficiaries who are hospital inpatients. The Congress did not address at that time nonphysician services furnished to Medicare beneficiaries who are hospital outpatients, for which payment is made, usually on a cost basis, under Part B of Medicare. Thus, services to hospital outpatients continued to be unbundled in some hospitals. Subsequently, in section 9343(c) of OBRA 1986, the Congress extended the bundling provision to all nonphysician services furnished to hospital ''patients,'' thus also including nonphysician services furnished to Medicare beneficiaries who are hospital outpatients.

Sections 9343(c)(1) and (c)(2) of OBRA 1986 amended sections 1862(a)(14) and 1866(a)(1)(H) of the Act, respectively. As revised, section 1862(a)(14) of the Act prohibits payment for nonphysician services furnished to hospital patients (inpatients and outpatients), unless the services are furnished by the hospital, either directly or under an arrangement (as defined in section 1861(w)(1) of the Act). As revised, section 1866(a)(1)(H) of the Act requires each Medicare-participating hospital to agree to furnish directly all covered nonphysician services required by its patients (inpatients and outpatients) or to have the services furnished under an arrangement (as defined in section 1861(w)(1) of the Act). Section 9338(a)(3) of OBRA 1986 affected implementation of the bundling mandate by amending section 1861(s)(2)(K) of the Act to permit services of physician assistants to be covered and billed separately.

Bundling of outpatient hospital services was required in order to provide a basis for implementing another provision of OBRA 1986, which required the development of a prospective payment methodology for outpatient hospital services. Section 9343(f) of OBRA 1986 amended section 1135 of the Act to require the Secretary to submit to the Congress by April 1, 1988, an interim report concerning development of a fully prospective payment system for ambulatory surgery. The legislation also specified that a final report was due to the Congress no later than April 1, 1989, with recommendations concerning implementation of a fully prospective payment mechanism for ambulatory surgery services by October 1, 1989. We released an interim report in June of 1988 and the final report in September of 1990. The final report summarized our research findings relating to hospital outpatient prospective payment and did not contain specific recommendations regarding a PPS for ambulatory surgical services. Later, in section 4151(b)(2) of OBRA 1990, the Congress expanded its earlier request and required HCFA to develop a PPS that included all hospital outpatient services. That legislation also directed us to submit a report to the Congress concerning this proposal. We submitted a report to the Congress on March 17, 1995.

In order for us to be able to develop a PPS for hospital outpatient services, it was necessary to have available clear and consistent rules about the range of services that would be included in this payment system. Previous policies on coverage of hospital outpatient services permitted services to be unbundled and thus allowed providers to vary their practices concerning the furnishing of services. The Congress recognized the inconsistencies of the current payment system and required bundling as a first step toward payment reform.

B. Previous Medicare Regulations Affecting Bundling

Previous regulations set forth at 42 CFR 405.310(m) concerning noncoverage of certain services furnished to hospital inpatients (redesignated as § 411.15(m)) implemented the statutory requirement for bundling of inpatient hospital services. They excluded from coverage nonphysician services furnished to hospital inpatients by an entity other than the hospital, unless the services were furnished under an arrangement. The exclusion from coverage in effect at that time did not apply to physician services that met the conditions for payment for physician services to provider patients in § 405.550(b) (redesignated as § 415.102(a)), or services of anesthetists employed by physicians that met the conditions for payment in § 405.553(b)(4) concerning reasonable charges for anesthesiology services furnished by the anesthesiologist or by an anesthetist employed by the anesthesiologist. (The regulation is now deleted as the payment structure for anesthesiologists has changed.) The exception for physician services is required by section 1862(a)(14) of the Act. Services of physician-employed anesthetists were exempted from bundling as an administrative measure to prevent disruption of long-standing physician-anesthetist team relationships. However, in a final rule published on May 26, 1993 (58 FR 30630), the regulations set forth at § 411.15(m) and § 489.20(d) were revised to reflect the statutory exclusion of certified registered nurse anesthetist (CRNA) services (including services of anesthesiologist assistants), physician assistant services, certified nurse midwife services, and qualified psychologist services from the inpatient bundling requirement. Section 411.15(m) concerns services to hospital inpatients excluded from coverage, and § 489.20(d) concerns a provider agreement in the case of a hospital or critical access hospital (CAH) to furnish directly or make arrangements for Medicare-covered services to inpatients of a hospital or a CAH.

C. Office of Inspector General (OIG) Civil Money Penalty Authority

In order to prevent the unbundling of nonphysician hospital services, section 9343(c)(3) of OBRA 1986 amended section 1866 of the Act by adding a new paragraph (g). Specifically, this

authority provided for the imposition of a civil money penalty (CMP), not to exceed $2,000, against any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment for a hospital outpatient service under Part B of Medicare that violates the requirement for billing under arrangements specified in section 1866(a)(1)(H) of the Act. Section 1866(g) was further amended by section 4085(i)(17) of OBRA 1987. Section 4085(i)(17) of OBRA 1987 deleted all references to hospital outpatient services under Part B of Medicare and authorized imposition of a CMP when arrangements should have been made but were not. Section 1866(g) of the Act authorizes imposition of a CMP against any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment inconsistent with an arrangement under section 1866(a)(1)(H) or in violation of the requirement for an arrangement. The result of this amendment is that the CMP is now applicable for all services furnished to hospital patients, whether paid for under Medicare Part A or B. The statute also requires that a CMP be imposed in the same manner as other CMPs are imposed under section 1128A of the Act. Section 231(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) revised section 1128A of the Act to increase the CMP maximum amount for each false claim or prohibited practice from $2,000 to $10,000. Implementing regulations for this authority are set forth in 42 CFR parts 1003 and 1005.

To implement the provisions of section 9343(c) of OBRA 1986, we published a proposed rule in the **Federal Register** on August 5, 1988 (53 FR 29486). Those regulations have not been published in final, but we are proposing revised implementing regulations as part of this regulation.

D. Proposed Regulations Published August 5, 1988

1. Bundling of Hospital Outpatient Services

We proposed to implement the requirement for bundling of outpatient hospital services by amending then existing Medicare regulations (§ 405.310 concerning particular services excluded from coverage, and part 410 concerning supplementary medical insurance benefits) to exclude coverage of any services that are furnished in a hospital to an outpatient of the hospital by an entity other than the hospital during or as a result of an encounter in the hospital, unless the services are furnished under an arrangement. In addition, we proposed to require bundling of those diagnostic procedures or tests (for example, magnetic resonance imaging procedures) that are furnished outside the hospital by an entity other than the hospital but are ordered during an encounter in the hospital with the patient or as a result of such an encounter.

In the proposed rule, in § 405.310(n)(1) concerning definitions of services to hospital outpatients excluded from coverage (now redesignated as § 411.15(m)), we defined a hospital outpatient as an individual who is not an inpatient of the hospital but who is registered as an outpatient.

We proposed to define, in § 410.2 (''Definitions''), the term ''encounter'' as a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, where applicable, by hospital staff bylaws, to order or furnish services for the patient for the purpose of diagnosis or treatment of the patient. The use of the ''encounter'' as a basis for identifying the services to be bundled is not specifically required by OBRA 1986 but is needed in order to implement the bundling requirement in a uniform and equitable manner, as explained further in section III. of the preamble of the August 5, 1988 proposed rule (53 FR 29489).

As in the case of services to hospital inpatients, physician services that meet the conditions for payment for services of physicians to provider patients in § 415.102(a) would not be bundled under our proposal. (The exception for physician services is required by section 1862(a)(14) of the Act.) We also proposed, as an administrative measure, to exempt from outpatient bundling the services of physician-employed anesthetists that meet the conditions for payment for services furnished by an anesthesiologist or by an anesthetist employed by the anesthesiologist in § 405.553(b)(4). These services were exempted from bundling to prevent disruption of long-standing physician-anesthetist team relationships. We also proposed to exempt physician assistant services as defined in section 1861(s)(2)(K)(i) of the Act from inpatient and outpatient bundling. We proposed this change to help accomplish the objective of section 1861(s)(2)(K)(i) of the Act, as amended by section 9338(a)(3) of OBRA 1986, which permits physician assistant services to be covered and to be billed separately. As noted earlier, we have made the changes in the types of services excluded from bundling of inpatient services in the May 1993 final rule (58 FR 30630).

We also proposed to revise the regulations set forth at § 489.20, which describe the basic commitments included in the provider agreement. They would require a hospital that furnishes services to a beneficiary who is not currently an inpatient of a hospital but who is registered by the hospital as an outpatient to agree either to furnish directly or to make arrangements (in accordance with section 1861(w)(1) of the Act) for all items and services for which bundling is required under the proposed revision described above, and for which the beneficiary is entitled to have payment made under Medicare.

We proposed in the August 5, 1988 proposed rule that if a Medicare outpatient is referred to another provider or supplier for further diagnostic testing or other diagnostic services as a result of an encounter that occurs in the hospital, the hospital would be responsible for arranging with the other entity for the furnishing of services. (We have now changed our view on bundling of these services as discussed in the following section IV.E.) Also, the hospital would be responsible for furnishing or arranging for the furnishing of prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses (IOLs)) and are implanted or fitted during an encounter. For example, in the absence of a bundling provision, the physician who implants an IOL during surgery performed on an outpatient of a hospital also could be the supplier of the IOL and could bill Medicare under Part B for it. As proposed in our August 1988 rule, this practice would be prohibited, and the hospital would have to furnish the IOL, either directly or under an arrangement (that is, would have to pay for the lens). The same policies would apply to other items and services, such as artificial limbs, knees, and hips; orthotics; equipment and supplies covered under the prosthetic device benefit; and services incident to physician services. Thus, hospitals would be required to assume financial liability for prostheses and prosthetic devices (which are regarded as ''services'' for Medicare coverage purposes) and for other services furnished by an outside entity to their outpatients, and the practice of unbundling these services would be prohibited.

Sometimes a hospital may furnish an item or service for which a patient will have a continuing need. For example, a hospital may furnish a DME item such as a wheelchair. When this situation occurs, the proposed rule required that

the hospital would be responsible for bundling the items and services it furnishes on-site. In adopting the view that these types of items are subject to bundling, we did not discount the patient's continuing need for them after leaving the hospital. However, the bundling provisions in sections 1862(a)(14) and 1866(a)(1)(H) of the Act prohibit unbundling of services to an individual who is a patient of a hospital and do not provide any specific exception to these provisions for DME. Therefore, we did not believe it would be appropriate to exclude DME from bundling when it was furnished to a hospital patient. (We have now changed our previous position on bundling of DME as discussed in section IV.E.)

2. Civil Money Penalties for Unbundling Hospital Outpatient Services

In order to implement section 1866(g) of the Act, in our August 5, 1988 proposed rule, we proposed that the OIG would impose a CMP against any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment for a hospital outpatient service under Part B of Medicare that violates the billing arrangement under section 1866(a)(1)(H) of the Act or the requirement for an arrangement. The amount of the CMP was to be limited to $2,000 for each improper bill or request, even if the bill or request included more than one item or service. However, in accordance with the Health Insurance Portability and Accountability Act of 1996, which increased the minimum penalty amount to $10,000, the increased amount will now be reflected in the regulations.

E. Revised Proposed Regulations on Bundling of Hospital Services

This proposed rule incorporates most of the provisions of the August 5, 1988 proposed rule. The following describes how the regulations published in this proposed rule to implement the rebundling of outpatient hospital services differ from the regulations we proposed and published on August 5, 1988:

- We are not including any of the changes in the regulations relating to payment for physician laboratory services (§§ 405.555(a) through (c), and 405.556(c) of the August 5, 1988 proposed rule), because these regulations were deleted as a result of publication of regulations to implement the Medicare physician fee schedule published on November 25, 1991 (56 FR 59502).
- We are revising § 409.10(b), which describes services that are not included in the definition of ''hospital inpatient or inpatient CAH services'' to include all of the services that are now exceptions from the bundling rule under section 1862(a)(14) of the Act. Section 4511 of the BBA revised sections 1862(a)(14) and 1866(a)(1)(H) of the Act to exclude services of nurse practitioners and clinical nurse specialists described in section 1861(s)(2)(K) of the Act from the bundling requirement.
- As previously indicated, proposed § 410.2 had been revised in the earlier proposed rule to include a definition of an ''encounter.'' The definition of an encounter is expanded to include encounters in a CAH. That section is further amended to include a definition of an ''outpatient'' as a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH. The revision to include CAHs in these definitions is made to comply with sections 1862(a)(14) and 1866(a)(1)(H) of the Act, which require that CAHs be treated as hospitals for purposes of the bundling provisions. (The BBA eliminated rural primary care hospitals (RPCHs) and created CAHs. The Congress intended, under section 4201(c) of the BBA, that CAHs be subject to the same Medicare requirements to which RPCHs were subject.)
- The revision to § 410.27 is the same as in the earlier proposed rule except that the revision is now designated as paragraph (e) instead of paragraph (c).
- We are removing paragraph (a)(4) of § 410.28 (''Hospital or CAH diagnostic services furnished to outpatients: Conditions'') to reflect a change made by section 4085(i)(11) of OBRA 1987 regarding provisions of diagnostic services furnished to outpatients.
- Proposed § 410.30 (redesignated as § 416.39 in this proposed rule) is being significantly revised. In § 410.30(a) and (b) (now § 410.39 (a) and (b) of regulations published on August 5, 1988, we proposed to require the hospital to furnish directly or under arrangements all services furnished to its outpatients during an encounter as well as any diagnostic services furnished outside the hospital that were ordered during or as a result of an encounter in the hospital. In this rule, we are not extending the bundling requirements to include diagnostic services ordered during an encounter in the hospital that are furnished outside the hospital. Thus, the hospital will not be required to furnish such diagnostic services directly or under arrangements. We are proposing a more limited approach to bundling because the PPS we are proposing involves less ''packaging'' than we anticipated when we published the August 1988 proposed regulations. At that time, we believed that a PPS payment for a surgical procedure was likely to include preoperative tests and that payment for a clinic visit was likely to include the ancillary services (for example, laboratory tests and x-rays) that were needed to make a diagnosis. Therefore, by requiring bundling of off-site diagnostic tests that were ordered during an outpatient encounter at the hospital, we believed we could ensure that: (1) We had sufficient data to set payment rates that included the ancillary tests, and (2) once the system was implemented, the bundling rules would prevent any duplication of program payments. That is, a service packaged into a PPS payment to the hospital could not also be billed to the program as an ancillary test by an outside entity.

  As noted above, the PPS we are proposing now does not include extensive packaging; therefore, the payment for related diagnostic tests is not included in the payments under the ambulatory payment classification (APC) groups for surgical procedures, clinic visits, emergency room visits, etc. Any diagnostic tests that are furnished will result in a separate payment. The program will pay the entity that actually furnishes the service—the hospital, if the service is provided directly or under arrangements made by the hospital; or another Medicare recognized entity, if the patient leaves the hospital and obtains the service elsewhere. Because diagnostic tests are not being packaged into another hospital service, we no longer need to require that a hospital furnish directly or under arrangements the services ordered during, or as a result of, an encounter, but furnished outside the hospital. If the PPS is changed in future years to require a more packaged approach to payment, the bundling regulations will be revised. Proposed § 410.30 (now § 410.39) is also revised to require that the bundling rules apply to CAHs, and the list of services that are excepted from the bundling requirements, in § 410.30(b) (now § 410.39(b)) (previously designated in the August 5, 1988, proposed rule as § 410.30(c)), is expanded to include all of the services that are currently excepted under section 1862(a)(14) of the Act.
- We are revising § 411.15(m) (previously designated as § 405.310(m)) significantly. We are eliminating proposed § 405.310(n). That section, which had described the hospital

outpatient services that were excluded from coverage if not furnished directly or under arrangements, has been revised so that we will not require that hospitals bundle diagnostic services ordered during or as a result of an encounter in the hospital if furnished outside the hospital. The requirements of that section have been incorporated into § 411.15(m)(1). We are revising § 411.15(m)(2), which describes the services that are exceptions to the bundling rule, to include all of the services that are now exceptions under section 1862(a)(14) of the Act. We are further revising § 411.15(m)(3), ''Scope of exclusion,'' to delete the reference to DME as a service that must be bundled. DME is defined under section 1861(n) of the Act as equipment used in the patient's home or in another institution used as his home other than a hospital or skilled nursing facility (SNF). By definition, DME is not something that is provided for use in the hospital setting. Therefore, we do not believe that the DME benefit provides for any item or service that is expected to be used by the patient while in the hospital as an inpatient or outpatient. Section 1862(a)(14) of the Act requires the hospital to provide directly or under arrangements services furnished to the patients of a hospital or CAH. We did not provide an exception for DME in our earlier proposed rule, because the bundling requirements under sections 1862(a)(14) and 1866(a)(1)(H) of the Act did not provide an exception for DME. However, we now believe that a statutory exception is not required because the bundling requirements apply to the services a hospital furnishes to its patients, and DME is not a hospital service. The covered Part B benefit for DME as described under section 1861(n) of the Act is intended for equipment used in the home, so a hospital that furnishes DME to its patients is not providing a hospital service to its patients, but is acting in the capacity of a supplier of DME, not a provider of hospital services. For these reasons, we will not require bundling of DME for hospital patients.

- Section 412.50 was not amended in the earlier proposed rule, but we are revising it in this rule to specify that hospital inpatient services do not include the services that are exceptions to the bundling requirements under section 1862(a)(14) of the Act.
- We are revising proposed § 489.20(d) to incorporate as exceptions to the bundling requirements all of the services that are now exceptions under section 1866(a)(1)(H) of the Act.
- In addition to minor wording changes in introductory paragraph (b), proposed § 1003.102 remains the same as in the August 5, 1988 proposed rule, with the exception that the revision is now designated as paragraph (b)(14) rather than as paragraph (b)(4), as originally indicated in the August 5, 1988 proposed rule. Paragraphs (b)(11) through (b)(13) of § 1003.102 are being reserved. We are also amending § 1003.103(a) to indicate, in accordance with section 231(c) of the Health Insurance Portability and Accountability Act, that the maximum CMP for each improper bill or request has been increased to $10,000.
- We are also amending § 1003.105 (Exclusion from participation in Medicare and State health care programs) by revising paragraph (a)(1)(i) to reflect that this basis for imposition of a CMP is also a basis for an exclusion from participation in Medicare and the State health care programs.

V. Hospital Outpatient Prospective Payment System (PPS)

In this proposed rule, we delineate the services that are covered under the hospital outpatient prospective payment system (PPS) that we are required to establish under section 1833(t) of the Act. We also propose Medicare payment rates when those services are ordered or furnished for diagnosis or treatment of a Medicare beneficiary who is registered on hospital records as an outpatient, and who receives services directly from the hospital.

In this section, we explain the framework for the hospital outpatient PPS. This framework rests on Medicare's definition of an outpatient, which we discuss in section IV.E, above, and on Medicare's definition of what constitutes a hospital outpatient department or clinic. In section VI., below, we address requirements to define and distinguish among the various sites where services that are covered under the hospital outpatient PPS could be furnished. For example, a service furnished at an outpatient department or clinic located within a hospital can also be furnished at a ''provider-based'' entity, at a site away from a hospital that functions as though it were a department within the hospital, at an ASC, and at a physician office. Under the statute as it is currently written, in order to determine whether Medicare makes payment for a service under the hospital outpatient PPS that is the subject of this proposed rule or under another provision of Medicare Part B, such as the ASC benefit or the physician fee schedule, it is essential to clarify exactly where and under what conditions the service was furnished.

This PPS will apply to covered hospital outpatient services furnished by any hospital participating in the Medicare program, except for those hospitals discussed below. Partial hospitalization services in community mental health centers (CMHCs) will also be paid under this PPS.

The cancer hospitals that are excluded from inpatient PPS will be paid under hospital outpatient PPS. Although the BBA provides for a separate conversion factor if necessary, we intend to pay cancer hospitals using the same conversion factor and rates as all other hospitals. Certain hospitals in Maryland furnish services that are exempt from this system because they qualify under section 1814(b)(3) of the Act for payment under the State's payment system. Such excluded services are limited to the services paid under the State's payment system as described in section 1814(b)(3) of the Act. Any other outpatient services furnished by the hospital will be paid under the outpatient PPS. Critical access hospitals are excluded from the outpatient PPS because they are paid under a reasonable cost based system, as required under section 1834(g) of the Act. All other participating hospitals will be paid under hospital outpatient PPS.

Distinct parts of hospitals that are excluded under inpatient PPS will be included in the outpatient PPS, to the extent that outpatient services are furnished by the hospital. For example, a hospital with an excluded inpatient psychiatric unit will have payment made under this PPS for outpatient psychiatric services including to inpatients who are not in a covered Part A stay.

A. Scope of Services Within the Outpatient PPS

Section 1833(t)(1)(B)(i) of the Act gives the Secretary the authority to designate which services are to be covered under the hospital outpatient PPS. In this section, we indicate the types of services for which we are proposing to make payment under the hospital outpatient PPS and the types of services we are proposing to exclude from the scope of the hospital outpatient PPS.

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for the services that she designates are covered under the hospital outpatient PPS. Section 1833(t)(2)(B) of the Act allows the Secretary to classify covered outpatient services by groups so that the services within each are comparable clinically and with respect to the use of resources.

We refer to the hospital outpatient PPS classification system that we have developed as the Ambulatory Payment Classification (APC) system. The APC system consists of 346 groups of services that are covered under the hospital outpatient PPS.

In section V.B., below, we explain how we assigned services and procedures to APC groups and in sections V.C. and V.D., below, we explain how we used the APC groups to determine hospital outpatient PPS payment rates.

1. Services Excluded From the Hospital Outpatient PPS

Section 1833(t)(1)(B)(iii) of the Act excludes the following from payment under the hospital outpatient PPS: ambulance services, physical and occupational therapy, and speech-language pathology services. These services will be paid under fee schedules in all settings.

Section 1833(t)(1)(B)(i) of the Act gives the Secretary the authority to designate which hospital outpatient services are covered under the outpatient PPS. In considering which services to include under the outpatient PPS, we wanted to ensure that all hospital outpatient services are paid under a prospectively determined amount. Some hospital outpatient services (for example, clinical diagnostic laboratory services, orthotics and prosthetics, ESRD dialysis services) are currently paid based on fee schedules or other prospective rates. Payments under these fee schedules apply not only to hospital outpatient services, but the same or very similar payment rates apply across a number of sites of ambulatory care. Such similar payments across various settings creates a level playing field where HCFA pays virtually the same payment for the same service, without regard to where the service is furnished. So that we do not disrupt an existing level playing field, we propose to exclude from our PPS, hospital outpatient services that are currently paid prospectively determined rates that are the same rates paid in other settings.

We are proposing to exclude from the hospital outpatient PPS the following:

a. Certain services already paid for under fee schedules or other payment systems including, but not limited to, services for patients with ESRD that are paid for under the ESRD composite rate; laboratory services paid under the clinical diagnostic laboratory fee schedule; and DME, orthotics, prosthetics, prosthetic devices, prosthetic implants and supplies (DMEPOS) paid for under the DMEPOS fee schedule when the hospital is acting as a supplier of these items. An item such as crutches or a walker that is given to the patient to take home, but that may also be used while the patient is at the hospital, would be billed to the DME regional carrier rather than being paid for under the hospital outpatient PPS.

b. Hospital outpatient services furnished to inpatients of an SNF regardless of whether the person is in a Part A covered stay and furnished pursuant to the resident assessment or comprehensive care plan and that are covered under the SNF PPS, furnished ''under arrangements'' and billable only by the SNF.

c. Services and procedures that require inpatient care.

MedPAC Recommendation: In its March 1998 report to the Congress, the Medicare Payment Advisory Commission (MedPAC) recommends that costs associated with allied health professions training, such as nursing schools and paramedical education, be excluded from the calculation of the relative weights and the conversion factor used to set outpatient PPS payment rates. MedPAC further recommends that Medicare make separate payment for these costs, consistent with the manner in which Medicare pays for allied health professions training costs under the inpatient PPS.

Response: We agree with MedPAC's recommendation. We did not include costs associated with allied health professions training in the calculation of outpatient PPS relative weights and conversion factors. We propose to pay hospitals that have allied health professions training programs on a cost-pass-through basis similar to the way we treat these costs under the hospital inpatient PPS.

2. Services Included Within the Scope of the Hospital Outpatient PPS

a. Services for Patients Who Have Exhausted Their Part A Benefits

Section 1833(t)(1)(B)(ii) of the Act provides for Medicare payment under the hospital outpatient PPS for certain services furnished to inpatients who have exhausted Part A benefits or otherwise are not in a covered Part A stay. Examples of services covered under this provision include diagnostic x-rays and certain other diagnostic services and radiation therapy covered under section 1832 of the Act.

b. Partial Hospitalization Services

Section 1833(a)(2)(B) of the Act provides that partial hospitalization services furnished in CMHCs be paid for under the hospital outpatient PPS. Partial hospitalization is a distinct and organized intensive psychiatric outpatient day treatment program, designed to provide patients with profound and disabling mental health conditions an individualized, coordinated, comprehensive, and multidisciplinary treatment program.

c. Services Designated by the Secretary

Under the authority established by the statute at section 1833(t)(1)(B)(i), we further are proposing to include within the scope of services for which payment is made under the hospital outpatient PPS the following:

- Services that are included within the outpatient PPS system are all hospital outpatient services that have not been identified for exclusion as described in section V.A.1., above. Among the types of services that we have classified into APC groups for payment under the hospital outpatient PPS are the following: surgical procedures; radiology, including radiation therapy; clinic visits; emergency department visits; diagnostic services and other diagnostic tests; partial hospitalization for the mentally ill; surgical pathology; cancer chemotherapy.
- Services furnished to SNF inpatients that are not packaged into SNF consolidated billing precisely because they are services that are commonly furnished by hospital outpatient departments and that SNFs would not be able to provide, such as CT scans, magnetic resonance imaging, or ambulatory surgery requiring the use of an operating room.
- Supplies such as surgical dressings that can be used during surgery or other treatments in the hospital outpatient setting that are also on the DMEPOS fee schedule. Payment for such supplies, when they are used in the hospital, is packaged into the APC payment rate for the procedure or service with which the items are associated.
- Certain preventive services furnished to healthy persons, such as colorectal cancer screening.

Section 4523(d)(3) of the BBA provides that we will make Part B payment for certain medical and other health services, when furnished by a provider of services or by others under arrangement with a provider of services, under the outpatient PPS, if we would otherwise pay those providers on a reasonable cost basis for those services. Specifically, we are proposing that we would pay for the following medical and other health services under the

outpatient PPS when furnished by a provider of services:

- Antigens (as defined in 1861(s)(2)(G) of the Act);
- Splints and casts (1861(s)(5));
- Pneumococcal vaccine, influenza vaccine, hepatitis B vaccine (1861(s)(10)).

We make Part B payment for the above services under the outpatient PPS when those services are provided by a CORF, HHA, or hospice program. However, this provision does not apply to services, furnished by a CORF, that fall within the definition of CORF services at section 1861(cc)(1) of the Act. It also does not apply to services furnished by a hospice within the scope of the hospice benefit. Nor does it apply to services furnished by HHAs to individuals under an HHA plan of treatment within the scope of the home health benefit.

3. Hospital Outpatient PPS Payment Indicators

Column B in Addendum B indicates the payment status of each HCPCS code. Addendum B displays all HCPCS codes, including those incidental services that are packaged into APC payment rates. Addendum G identifies inpatient services not payable under outpatient PPS.

- We use ''A'' to indicate services that are paid under some other method such as the DMEPOS fee schedule or the physician fee schedule.
- We use ''E'' to indicate services for which payment is not allowed under the hospital outpatient PPS or is not covered by Medicare.
- We use ''C'' to indicate inpatient services that are not payable under the outpatient PPS.
- We use ''N'' to indicate services that are incidental, with payment packaged into another service or APC group.
- We use ''P'' to indicate services that are paid only in partial hospitalization programs.
- We use ''S'' to indicate significant procedures for which payment is allowed under the hospital outpatient PPS but to which the multiple procedure reduction does not apply.
- We use ''T'' to indicate surgical services for which payment is allowed under the hospital outpatient PPS. Services with a payment indicator ''T'' are the only services to which the multiple procedure payment reduction applies.
- We use ''V'' to indicate medical visits for which payment is allowed under the hospital outpatient PPS. Providers must use ICD–9–CM (International Classification of Diseases, Ninth Edition, Clinical Modification) codes to determine the level of payment for services with a payment indicator ''V''.
- We use ''X'' to indicate ancillary services for which payment is allowed under the hospital outpatient PPS.

The table below lists all of the outpatient PPS indicators and what they designate.

STATUS INDICATORS

[How Medicare Pays for Various Services When They Are Billed for Hospital Outpatients]

Indicator	Service	Status
A	Pulmonary Rehabilitation; Clinical Trial	Non-paid.
C	Inpatient Procedures	Bill as Inpatient.
A	Durable Medical Equipment, Prosthetics and Orthotics	DMEPOS Fee Schedule.
E	Non-covered Items and Services	Non-paid.
A	Physical, Occupational and Speech Therapy	Rehab Fee Schedule.
A	Ambulance	Ambulance Fee Schedule.
A	EPO for ESRD patients	National Rate.
A	Clinical Diagnostic Laboratory Services	Lab Fee Schedule.
A	Physician Services for ESRD patients	Bill to carrier.
A	Screening Mammography	Lower of Charge or National Rate.
N	Incidental Services, packaged into APC Rate	Packaged; no additional payment allowed.
P	Partial Hospitalization Services	Paid per diem.
S	Significant Procedure, not reduced when multiple	Paid under hospital outpatient PPS (APC rate).
T	Significant Procedure, multiple procedure reduction applies	Paid under hospital outpatient PPS (APC rate).
V	Visit to Clinic or Emergency Department	Paid under hospital outpatient PPS (APC rate).
X	Ancillary Service	Paid under hospital outpatient PPS (APC rate).

B. Description of the Ambulatory Payment Classification (APC) Groups

In response to OBRA 1986 and OBRA 1990 requirements to develop a hospital outpatient PPS, we examined systems that were in place or under development, and we entered into a cooperative agreement with 3M-Health Information Systems to develop a classification system for outpatient services. The results of our review of existing systems are outlined in a Report to Congress dated March 17, 1995. The report identified the Ambulatory Patient Groups (APGs), which were developed by 3M-Health Information Systems, as the most promising classification system, and we recommended that APG-like groups be used as the basis for the hospital outpatient PPS. Soon after the report was submitted to the Congress, 3M-Health Information Systems released an updated version (known as Version 2.0) of the APGs. Since the release of Version 2.0, HCFA has revised the APGs based on more recent Medicare data. These revisions constitute what we are calling the Ambulatory Payment Classification (APC) system or groups that are proposed in this rule. Services within the APC system are identified by HCPCS codes and descriptions.

1. Setting Payment Rates Based on Groups of Services Rather Than on Individual Services

MedPAC Recommendation: In its March 1998 report to the Congress entitled ''Report to the Congress: Medicare Payment Policy,'' MedPAC recommends that payment rates under the hospital outpatient PPS be based upon relative weights for each individual service rather than upon groups of similar services to help ensure consistent payments across ambulatory settings. MedPAC gives several reasons to support this recommendation:

- If services in a group are not homogeneous, a single payment rate for

all services in the group would not be accurate.

- Hospitals whose case mix includes a greater than average volume of higher-cost procedures in a group with a payment rate based on median costs for all procedures in the group could face losses and would have a financial incentive to provide only the lower-cost procedures within a group and to avoid the higher-cost procedures.
- Grouping services creates considerable administrative burdens and problems related to data consistency, provider education, the need for extensive technical assistance, and modification of claims processing systems.
- If costs for services in a group change at different rates, the price for the group may become distorted over time, necessitating periodic rebasing of group weights.
- Using groups to set rates for services under the hospital outpatient PPS moves away from standardizing payment systems across ambulatory settings.

Response: We have carefully reviewed MedPAC's concerns about using groups of services rather than individual services as the basis for setting weights under the hospital outpatient PPS, and we believe that we have addressed most of these concerns in our approach to ratesetting using APC groups.

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered outpatient services. Section 1833(t)(2)(B) provides that this classification system may be composed of groups, so that services within each group are comparable clinically and with respect to the use of resources. The statute refers to ''each such service (or group of services),'' implying that we may choose or not choose to group services. We have chosen to set rates for groups of similar services rather than setting rates for individual services for several reasons:

- The composition of the APC groups is based on two premises: the procedures within each group must be similar clinically, and the procedures must be similar in terms of resource costs. As we explain below, we used 3M's APGs as a starting point, but we have subsequently made changes to most of the 3M groups, taking into account 1996 outpatient claims data; data collected in a 1994 survey of ASC costs and charges; data collected in 1995 and 1996 to establish resource-based practice expense relative values under the Medicare physician fee schedule; comments on surgical groupings following an ASC town meeting held at HCFA in July 1996 at which participants reviewed 3M's Version 2.0 surgical APGs for consistency in terms of clinical characteristics and resource costs; and the medical judgment of HCFA's medical advisors. Further, we invite comments on the composition of all the APC groups that are presented in this proposed rule and whether readers believe that further refinements are needed. We request that commenters support their recommendations for changes in the APC groups with data regarding resource costs (time, supplies, equipment, labor requirements) as well as clinical arguments.

We have also solicited comments on the same surgical APC groups that are proposed in this rule as part of a proposed rule entitled ''Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998'' (HCFA–1885–P), published in the **Federal Register** June 12, 1998 (63 FR 32290). We intend to coordinate our review of all comments submitted timely during the comment period for the hospital outpatient PPS proposed rule and the ASC proposed rule. Any subsequent changes to the APC groups will be used by both payment systems when we set their respective final rates. We have a high level of confidence in the homogeneity of the APC groups that will emerge from this exhaustive review process.

- We have found that, in this context, setting weights at a single code level suggests a level of precision that is often not warranted due either to low procedure volume or questionable cost data.
- Of the 10,500 codes in the HCPCS, over 5,000 describe services that are covered under the hospital outpatient PPS. However, an examination of outpatient claims data for 1997 reveals that as few as 100 HCPCS codes account for more than a third of all coded services billed during that year. MedPAC states in its report to the Congress that its analysis of physician claims for 1996 revealed that more than 90 percent of hospital outpatient volume was accounted for by 300 high volume services. Because so many codes were billed infrequently or not at all, we found ratesetting to be facilitated by grouping together the data that were available for codes that are similar clinically. We disagree with MedPAC's suggestion that we establish payment groups composed only of low-volume procedures. If we were to establish such groups, we would either have to except these groups from the principle of clinical consistency that applies to other APC groups or greatly increase the number of APC groups within the outpatient PPS. And, this approach does not solve the problem of how to establish weights for procedures, whether they are taken individually or in groups, for which we have inadequate cost data. Placing low Medicare volume procedures in APC groups with which they are similar clinically and in terms of resource consumption does not affect the weight established for the group to any appreciable extent because the weight derives from the higher volume procedures within the group.
- Grouping closely related services, and paying the median cost of the group, discourages the upcoding that occurs when individual services that are similar have disparate median costs.
- Using APC groups to set outpatient weights is consistent with the ratesetting method we are proposing for ASCs. In a proposed rule entitled ''Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998'' (HCFA–1885–P), published in the **Federal Register** June 12, 1998 (63 FR 32290), we propose payment rates for surgical procedures performed in Medicare-approved ASCs using APC surgical groups proposed in this rule.
- Payment rates for new or redefined services can be more reliably established by assigning codes for these services to an existing group of several codes that share characteristics with the new code rather than trying to match it to an equivalent single procedure for which we may or may not have reliable cost data.
- Our experience basing ASC payment rates on groups of codes has proved to be no more burdensome administratively than has our experience with setting weights on a single code basis under the Medicare physician fee schedule. Under the outpatient PPS, with weights set by APC groups, hospitals will continue to use the same HCPCS coding and the same claims forms that they use currently. Any burdens on HCFA or on hospitals necessitating additional technical assistance or systems changes are more a function of implementing an entirely new payment system than of our setting weights on the basis of groups of services instead of on the basis of single procedures or services.

We invite comments on our setting rates on the basis of groups of services rather than on individual codes.

2. How the Groups Were Constructed

3M created APGs by combining procedure codes and diagnosis codes into groups that were clinically related (such as all codes for repair of fractured legs) and analyzing claims data to determine if the codes that were clinically similar also used resources in similar ways (for example, surgical repair would likely be more resource intensive than closed manipulation and casting). The resources that were examined were based on a 3-month sample of all Medicare claims for outpatient services. The sample of nearly 15 million claims was selected from claims paid in 1992 with the charges on each claim matched to departmental cost-to-charge ratios from the hospital that provided the services. The costs that were calculated using billed charges and department cost-to-charge ratios included direct costs, as well as the overhead for performing the services. The APGs were clustered into significant procedures (both surgical and nonsurgical), medical visits (in both clinics and emergency departments), and ancillary services. Other groups captured incidental services (those that would not be paid separately) and procedures for which no payment is made, such as services specifically excluded from Medicare payment by statute.

Our Report to Congress recommended the use of APG-like groups for a hospital outpatient prospective payment system. When the time came to update payment groups for ASCs, which already were paid under a PPS, we decided to propose the use of APG-like groups. The ASC industry was accustomed to eight payment groups, with rates ranging from about $300 to about $900 in roughly $75 increments, without clinical coherence. While interested in our proposal, the ASCs were concerned about perceived misclassifications, with groups containing codes they believed represented divergent resources. To accommodate these concerns, we regrouped many surgical codes, creating more levels within some ranges of groups and otherwise changing 3M's system. We also found it necessary to change the medical APGs. The medical visit groups, which under the APGs were grouped based on the patient's diagnosis, were clearly distinct when laboratory services and plain film x-rays were packaged in, but were much less distinct when those ancillary services related to the visit were not packaged, as will be the case initially under our system. We therefore investigated other approaches to categorizing medical visits that would result in clearly defined payment groups without extensive packaging. We discuss these approaches in section V.B.4., below.

This process of revising 3M's APGs resulted in the development of the set of 346 mutually-exclusive and exhaustive service categories called ambulatory payment classification groups or APCs. The weights of the groups proposed in this rule are based on new data, as required by the BBA. We matched the database of 98 million hospital outpatient claims paid in 1996 to the most recent available cost reports for each hospital, and constructed the groups using these cost data. We defined each outpatient service under the PPS by a HCPCS code and classified it either into one of the APC groups for which an outpatient PPS payment rate is established or into a non-payment category of services that are excluded from the outpatient PPS. A weight is associated with each APC group. See section V.C. of this rule for details on how we calculated the weights. Procedures and services assigned a non-payment classification include services that can be provided only on an inpatient basis; codes or services that are not covered by Medicare; and procedures and services paid under fee schedules or other payment method.

3. Packaging Under the Groups

Packaged services are those that are recognized as contributing to the cost of the services in an APC, but that we do not pay for separately. Under the APC system, packaged services include the operating room, recovery room, anesthesia, medical/surgical supplies, pharmaceuticals, observation, blood, intraocular lenses, casts and splints, donor tissue, and various incidental services such as venipuncture. We ''packaged'' the services (and their costs) within the APC group of procedures with which they were delivered in the base year. Below is a list of the hospital revenue centers from which we derived costs that were packaged within the APC groups. For example, a given surgical procedure would have a cost for the use of the operating and recovery rooms in every case. However, supply costs might vary, with some patients requiring special drains and dressings and others needing minimal dressings. The average packaged cost for supplies might represent, for example, $200 for the former group 40 percent of the time, and $150 for the rest. Thus, the APC would include $170 for supplies. Similarly, only a few cases would have included observation in the base year, but each case in the group would include a small amount for the times we associated observation with the cases in the group.

We have packaged the cost of pharmaceuticals and biologicals within APC groups. We did this because we believe drugs are usually provided in connection with some other treatment or procedure. We have captured aggregate cost data on all drugs that were billed with HCPCS codes and those billed with revenue center codes, whether or not a HCPCS was entered. Thus, historical patterns of drug use are captured within the APC groups with which the drugs were billed during the base year. The only separate drug groups we have created are for chemotherapeutic agents, because those were separately identified in 3M's APG system. Because we intended to use an APG-like system, we required detailed coding of chemotherapeutic agents in order to be able to capture the costs of the specific drugs. We did not require HCPCS coding of other drugs, so we cannot specifically identify costs of non-chemotherapy drugs. We understand, however, that some rarely-used drugs are both expensive and used in only a few hospitals. In those instances, APC payment rates may not adequately represent costs for hospitals that treat patients who require infusions of very costly drugs or biologicals. Because we do not have bills that were coded to identify these high-cost drugs individually, we cannot evaluate the impact of paying separately for high-cost drugs. We could require HCPCS coding of all drugs or certain categories of drugs in order to gather the data, but we know hospitals could find such a requirement burdensome. We solicit comments on this issue.

Currently, drugs that can be self-administered are not covered under Part B of Medicare (with certain specific exemptions for blood-clotting factors, immunosuppresives, erythropoietin for dialysis patients, and certain oral chemotherapeutic agents and antiemetics). This presents problems in the outpatient hospital setting because even a pain killer given to a groggy patient postoperatively would not be covered. The only way such drugs can be paid for is for the hospital to bill the beneficiary. In many cases, the hospital does not, both because keeping track of such small charges for billing purposes is burdensome and because beneficiaries would not understand why they are being asked to pay for, for example, pain medication that was clearly related to the procedure they had undergone.

We propose to allow hospitals to provide drugs to patients without requiring that the hospital bill the

patient, and without Medicare's paying the hospital. Normally, hospitals are not allowed to waive such billing, since not charging a patient could be seen as an inducement to the patient to use other services at the hospital, for which the hospital would be paid. However, if the benefit is not advertised, we believe that provision of the self-administered drugs at no charge to the beneficiary need not constitute an inducement in violation of the anti-kickback rules. The hospital may not advertise this to the public or in any other way induce patients to use the hospital's service in return for forgoing payment.

Recommendation: MedPAC recommends that the unit of payment under the outpatient PPS be the individual service or procedure that is furnished and that payment for services and supplies integral to the individual service or procedure be bundled within that single unit of payment.

Response: We agree both with MedPAC's recommendation regarding what should constitute the unit of payment under the outpatient PPS, and with MedPAC's recommendation regarding the ''bundling'' of payment, which we call ''packaging,'' for supplies and services that are integral to the individual service or procedure that constitutes the unit of payment. All services and procedures for which payment is to be made under the outpatient PPS are identified by HCPCS codes and descriptions. This approach of identifying individual services by HCPCS as the unit for payment parallels the unit for payment under both the Medicare physician fee schedule and the ASC facility services benefit. In addition, as we explain above, the payment amount for each HCPCS code is a packaged payment that takes into account the costs associated with services and supplies that are integral to the primary HCPCS-coded service or procedure and that are furnished at the same time and in the same place as the primary service or procedure. Because we modeled the outpatient PPS package of services for surgical procedures on the package of services that is the basis for payments for facility services furnished by Medicare approved ASCs, the definition of packaging will become standardized across both settings upon implementation of the outpatient PPS.

MedPAC cites as a disadvantage of using individual services or procedures as the unit for payment the limited options that are available to control the volume of unnecessary ancillary services. We discuss in section V.J. how we intend to address volume control under the outpatient PPS. While a broader definition of packaging that includes related ancillaries such as diagnostic x-rays and other diagnostic tests that are furnished in other settings or at a different time than the primary service or procedures may have potential benefits not realized by the more limited packaging that we are using, we are concerned that applying different definitions of packaging to payments for the same primary service furnished in different settings would defeat the goal of establishing a unified payment structure across sites. One component of achieving this goal is to employ a consistent definition of packaging across all sites of ambulatory services. We solicit comments on the packaging options and the implications for ratesetting and volume control of using the same or different definitions of packaging across different settings.

The following table identifies by revenue code the services and items that are packaged into the various categories of APC groups (surgery, radiology, other diagnostic, medical visits, and all other APC groups).

PACKAGED SERVICES BY REVENUE CENTER

SURGERY

250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
257	NONPRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER.
270	M&S SUPPLIES.
271	NONSTERILE SUPPLIES.
272	STERILE SUPPLIES.
360	OPERATING ROOM.
361	MINOR SURGERY.
369	OTHER.
370	ANESTHESIA.
379	OTHER.
380	''BLOOD, GENERAL CLASS''.
381	PACKED RED CELLS.
382	WHOLE BLOOD.
383	PLASMA.
384	PLATELETS.
385	LEUCOCYTES.
386	OTHER COMPONENTS.
387	OTHER DERIVATIVES.
389	OTHER BLOOD.
390	BLOOD STORAGE AND PROCESSING.
391	BLOOD ADMINISTRATION.
399	OTHER BLOOD PROC/STORAGE.
490	''AMBULATORY SURGERY, GENERAL CLASS''.
491	OTHER AMBULATORY SURGICAL CARE.
630	DRUGS REQUIRING ID.
631	SINGLE SOURCE DRUG.
632	MULTIPLE SOURCE DRUG.
636	DRUGS REQUIRING DETAILED CODING.
700	CAST ROOM.
709	OTHER.
710	RECOVERY ROOM.
719	OTHER.
720	LABOR ROOM.
721	LABOR.
722	DELIVERY.
723	CIRCUMCISION.
724	BIRTHING CENTER.
729	OTHER.
750	GASTROINTESTINAL.
759	OTHER.
760	OBSERVATION ROOM.
761	TREATMENT ROOM.
762	OBSERVATION ROOM.
769	OTHER TREATMENT ROOM.
890	OTHER DONOR BANK.
891	BONE.
892	ORGAN.
893	SKIN.
899	OTHER.
920	''OTHER DIAGNOSTIC SERVICES, GENERAL CLASS''.
929	OTHER DIAGNOSTIC SERVICES.
940	''OTHER THERAPEUTIC SERVICES, GENERAL CLASS''.
949	OTHER THERAPEUTIC SERVICES.

MEDICAL VISIT

250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
257	NONPRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER.
270	M&S SUPPLIES.
271	NONSTERILE SUPPLIES.
272	STERILE SUPPLIES.
279	OTHER.
380	''BLOOD, GENERAL CLASS''.
381	PACKED RED CELLS.
382	WHOLE BLOOD.
383	PLASMA.
384	PLATELETS.
385	LEUCOCYTES.
386	OTHER COMPONENTS.
387	OTHER DERIVATIVES.
389	OTHER BLOOD.
390	BLOOD STORAGE AND PROCESSING.
391	BLOOD ADMINISTRATION.
399	OTHER BLOOD PROC/STORAGE.
630	DRUGS REQUIRING ID.
631	SINGLE SOURCE DRUG.
632	MULTIPLE SOURCE DRUG.
636	DRUGS REQUIRING DETAILED CODING.
762	OBSERVATION ROOM.

DIAGNOSTIC

250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
254	INCIDENT TO OTHER DIAGNOSTIC.
257	NONPRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER.
270	M&S SUPPLIES.
271	NONSTERILE SUPPLIES.
272	STERILE SUPPLIES.
360	OPERATING ROOM.
361	MINOR SURGERY.
369	OTHER.
370	ANESTHESIA.
372	INCIDENT TO OTHER DIAGNOSTIC.
379	OTHER.
380	''BLOOD, GENERAL CLASS''.
381	PACKED RED CELLS.
382	WHOLE BLOOD.
383	PLASMA.
384	PLATELETS.
385	LEUCOCYTES.
386	OTHER COMPONENTS.
387	OTHER DERIVATIVES.
389	OTHER BLOOD.
390	BLOOD STORAGE AND PROCESSING.
391	BLOOD ADMINISTRATION.
399	OTHER BLOOD PROC/STORAGE.

PACKAGED SERVICES BY REVENUE CENTER—Continued

450	ER.
459	OTHER.
622	INCIDENT TO OTHER DIAGNOSTIC.
630	DRUGS REQUIRING ID.
631	SINGLE SOURCE DRUG.
632	MULTIPLE SOURCE DRUG.
636	DRUGS REQUIRING DETAILED CODING.
710	RECOVERY ROOM.
719	OTHER.
762	OBSERVATION ROOM.

RADIOLOGY

250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
255	INCIDENT TO RADIOLOGY.
257	NON-PRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER.
270	M&S SUPPLIES.
271	NONSTERILE SUPPLIES.
272	STERILE SUPPLIES.
360	OPERATING ROOM.
361	MINOR SURGERY.
369	OTHER.
370	ANESTHESIA.
371	ANESTHESIA INCIDENT TO RADIOLOGY.
379	OTHER.
380	"BLOOD, GENERAL CLASS".
381	PACKED RED CELLS.
382	WHOLE BLOOD.
383	PLASMA.
384	PLATELETS.
385	LEUCOCYTES.
386	OTHER COMPONENTS.
387	OTHER DERIVATIVES.
389	OTHER BLOOD.
390	BLOOD STORAGE AND PROCESSING.
391	BLOOD ADMINISTRATION.
399	OTHER BLOOD PROC/STORAGE.
621	SUPPLIES INCIDENT TO RADIOLOGY.
630	DRUGS REQUIRING ID.
631	SINGLE SOURCE DRUG.
632	MULTIPLE SOURCE DRUG.
636	DRUGS REQUIRING DETAILED CODING.
710	RECOVERY ROOM.
719	OTHER.
762	OBSERVATION ROOM.

ALL OTHER APC GROUPS

250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
257	NONPRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER.
270	M&S SUPPLIES.
271	NONSTERILE SUPPLIES.
272	STERILE SUPPLIES.
279	OTHER.
380	"BLOOD, GENERAL CLASS".
381	PACKED RED CELLS.
382	WHOLE BLOOD.
383	PLASMA.
384	PLATELETS.
385	LEUCOCYTES.
386	OTHER COMPONENTS.
387	OTHER DERIVATIVES.
389	OTHER BLOOD.
390	BLOOD STORAGE AND PROCESSING.
391	BLOOD ADMINISTRATION.
399	OTHER BLOOD PROC/STORAGE.
630	DRUGS REQUIRING ID.
631	SINGLE SOURCE DRUG.
632	MULTIPLE SOURCE DRUG.

PACKAGED SERVICES BY REVENUE CENTER—Continued

636	DRUGS REQUIRING DETAILED CODING.
762	OBSERVATION ROOM.

4. Treatment of Clinic and Emergency Visits

The major issue we face in determining payment for clinic and emergency room visits is whether to include diagnosis as well as *Physicians' Current Procedural Terminology* (CPT) codes in setting payment rates. We solicit comments on the approaches that we discuss below and on other possible alternatives.

Determining payment for clinic and emergency room visits requires a variety of considerations and trade-offs. These include:

- The impact of packaging on setting payment rates (for example, the more packaging, the greater the difference among APC payments; however, we are not proposing a fully packaged system initially, which reduces payment differences and may necessitate additional policies to increase differences across payment groups);
- How to code visits in a manner that recognizes variations in service intensity and levels of resource consumption (for example, how to pay more for visits that cost more);
- How to keep the system administratively manageable (for payment purposes, we assign 31 CPT codes that describe different levels of evaluation and management services to 7 APC groups);
- How to define critical care in terms of facility as opposed to physician inputs (for example, what is an appropriate facility payment for critical care when critical care CPT codes are currently determined to reflect physician inputs);
- Data problems associated with identifying costs from claims that list multiple services (for example, the data analysis we have conducted so far reflects only data from claims for single visits; we are analyzing data from multiple visit claims to glean additional information relevant to these policies);
- How to move toward greater uniformity of payments across ambulatory settings so as to remove payment as an incentive for determining site of service (for example, the trade-off that could result if, by enhancing differentiation of payments for services within the hospital outpatient setting, we were to increase payment differences across settings for services that are provided in both hospital outpatient departments and physician offices).

Given the range of issues surrounding payments for clinic and emergency room visits, we are continuing to weigh different options. We are concerned that using diagnosis coding to set rates for hospital outpatient clinic visits could increase disparities in payment methodology between outpatient departments and physician offices, for which a new system of resource based practice costs is just now being proposed. (These concerns do not extend as much to emergent and critical care, which are not routinely furnished in physician office settings.) Diagnostic coding has not been used in the past to adjust payments in the physician office setting and there is no general evidence that practice expense (or work) in physician office settings varies by the patient's diagnosis. Moreover, because patients in the hospital outpatient department can be shifted easily to alternative outpatient settings, adjustment of facility costs to take diagnosis into account in one setting but not others may create incentives to shift patients among ambulatory settings in unknown ways.

Coding Visits

We have considered several approaches to setting prospective payment rates for hospital clinic and emergency visits. We reviewed the medical visit groups in 3M's version 2.0 of APGs that are based solely on ICD–9 diagnosis codes, with 80 APGs providing several groups for each body system; we analyzed the effect on ratesetting of defining clinic and emergency visits solely by CPT code; and, we analyzed the effect of using a matrix that combines patient diagnosis with a CPT code to describe the nature of the outpatient encounter. We discuss these various approaches in more detail here and some of the advantages and disadvantages of each. Again, we solicit comments on these approaches to setting payment rates for clinic and emergency room visits as well as comments on alternative approaches that are not mentioned here.

Approach 1: Using Diagnosis Codes Only

3M's approach of using only ICD–9 diagnosis codes with extensive packaging results in a wide range of group payment rates. The group that pays the most is almost 13 times as costly as the lowest-paid group. However, when we removed minor laboratory tests, x-rays, and certain other minor procedures that had been packaged into 3M's medical visit APGs in order to conform with the packaging that we propose in this proposed rule,

the difference between the highest and the lowest paid group dropped to not quite five times. (Fully packaged APGs are sufficiently differentiated for payment purposes, while partially packaged APGs are not; therefore, if we were to move to a fully packaged system, we would re-evaluate approaches using diagnosis.)

We also found that grouping clinic and emergency visits solely on the basis of diagnoses tends to result in visits that require major resources for critical cases clustering together with less resource-intensive follow-up visits after the crisis has passed.

Approach 2: Using CPT Codes Only

The APC groups that we propose in this proposed rule as the basis for setting rates for surgical services consist solely of CPT codes. We looked at using only CPT codes to establish payment groups for outpatient clinic and emergency room visits, but we found that the variation between the most costly and the least costly encounter was quite flat, with the former only 4.5 times greater than the latter. When basing payment on CPT codes alone, the range reflects hospitals' billing patterns in increasing level of intensity, but cases at the margin are overwhelmed by the numbers of visits billed so that individual cases with low or high costs are not discernible. Also, billing patterns reflect standard bills, not the resources used in any particular case.

Approach 3: CPT and Diagnosis Hybrid

We looked at another approach that bases payment rates on a hybrid of CPT codes and patient diagnoses. We first assigned 31 CPT codes that describe physician encounters with patients in the outpatient setting to seven APC groups: three for clinic visits, three for emergency department visits, and one for critical care. We also collapsed approximately 12,000 ICD–9 codes into 20 major diagnostic categories (MDCs), arranged generally by body system. Classifying services in this fashion produces a more manageable number of groups, and results in a matrix of 121 CPT/diagnosis combinations, in which the most costly combination is more than 10 times as costly as the least.

Our grouping of evaluation and management CPT codes was based on several factors. As we note above, we grouped 31 CPT codes that represent different levels of physician ''evaluation and management'' of patients into seven APC groups. (For a more complete discussion, refer to the evaluation and management services guidelines in Physicians' *Current Procedural Terminology* 1998 edition (CPT '98) published by the American Medical Association.) CPT codes are more descriptive of physician effort than of facility use, and our cost data showed little difference between level 1 and level 2 visits or between level 4 and level 5 visits. Therefore, we elected to combine some of the CPT codes into a single group, for example, the two least intensive outpatient visit codes, 99201 and 99202, are both in APC 911, which is the lowest level of clinic visits, etc. Grouping CPT codes together in this fashion reduces administrative burden, and our data analysis shows only small additional cost differences among the complete set of CPT medical visit codes. Moreover, we found that grouping CPT codes in this fashion evens out certain anomalies that arise when an emergency department furnishes services that would not typically be thought of as emergency care, such as suture removal, or treatment of a skin disease. Even though suture removal or treatment of conditions such as impetigo, conjunctivitis, etc. is performed in emergency departments, these types of services are more appropriately furnished at a clinic because they do not require the more elaborate resources of the emergency department. Assigning codes to APC groups would allow us to set payment for care of patients with minor problems in the emergency department at a level equivalent to payment for the same care when it is furnished at a clinic. We welcome comments on payment for services that do not require emergency room use.

Using a matrix of evaluation and management codes with patient diagnosis would offset the disadvantages noted above of grouping solely by CPT code (too little payment variation) or solely by patient diagnosis (reduced payment variation and commingling of resource intensive and non-resource intensive visits). Defining a clinic or emergency visit APC in terms of both CPT code and diagnosis, even when grouping codes to provide a manageable number of groups, would better recognize the facility resources consumed in providing emergency and critical care visits. Many such visits, of course, cluster around the same dollar amount, but this is expected because many visits involve typical care and standard resources. The cases that represent care at higher or lower levels of intensity appear to represent real differences in resource consumption. We used the CPT/patient diagnosis hybrid to model impacts. We do not believe that payment to individual hospitals would be significantly affected, whether we base payment rates on groups of CPT codes only or on groups that combine CPT codes and patient diagnosis.

Using a matrix that combines CPT codes with patient diagnosis to set payment rates for clinic and emergency department visits would also improve the coding of diagnoses in the hospital outpatient setting generally. Such improved diagnosis coding is critical to evaluating future degrees of packaging in the APC system, and we have already noted that more packaging tends to increase the measured cost differences across APC groups.

However, as we discussed earlier, there are also problems with using a matrix that includes diagnosis codes for hospital outpatient visits. We are concerned about the effect of using a method to pay for clinic visits in the hospital outpatient setting that is at variance with the method we use to pay for the same service in a physician office. A possible alternative to using diagnosis codes as an indicator of resource consumption in connection with medical visits in hospital outpatient departments is to create a uniform fee schedule for physician visits across all ambulatory settings, paying the site at which the service is furnished the physician practice expense component as a ''facility fee.'' However, the latter option would require legislation and a possible reallocation of the overhead currently associated with medical visits in the outpatient department to other outpatient services. Given the complexity of these issues, it may not be desirable to introduce additional differences, such as diagnosis, among payments in medical visits at this time. We invite public comment on all of the issues raised in the discussion in this section. In addition, after this rule is published, we will be reexamining our outpatient database and extending our analysis to multiple visit data. We will incorporate the findings of these additional analyses into our final decision.

Hypothetical Case Using the Hybrid

The following is a hypothetical case presented to illustrate how payment would be determined using the CPT code/diagnosis code hybrid. A new patient, an elderly woman who has recently come to live with her family in the area, presents to the primary care clinic complaining of fatigue, shortness of breath, swollen ankles, and loss of vision. The physician spends 45 minutes eliciting the patient's medical, family, and social history and performing an extensive physical examination. Suspecting cataracts as the

cause of her loss of vision, the physician suggests she make an appointment in the eye clinic. Suspecting congestive heart failure as the cause of her other symptoms, but also suspicious of coexisting diabetes and hypertension, the physician orders laboratory tests and an electrocardiogram (ECG) to be performed that day, and schedules an appointment in the cardiovascular clinic for a later date. If payment to the hospital were to be made on the basis of a CPT code/ICD–9 code matrix, the hospital's claim for services furnished in connection with this visit would identify the following information: CPT code 99204, comprehensive outpatient visit, new patient, and ICD–9 diagnosis code 401.1, benign hypertension. Payment would be determined by mapping CPT code 99204 to APC group 915, levels 4 and 5 clinic visit, and ICD–9 code 4011 to MDC 36, cardiovascular system diseases. Payment would be the rate established for the resulting hybrid group identifier, 91536. Addendum A lists the payment rates for the proposed hospital clinic and emergency room payment groups. Separate payment would be made under the clinical diagnostic laboratory fee schedule for the laboratory work; the ECG would be paid for separately on the basis of the payment rate established for APC 950.

Several months later, the same patient, who now is known to have congestive heart failure, returns to the primary care clinic complaining of a cough and runny nose. The physician, having determined that the symptoms are due to a virus, recommends using a humidifier and drinking extra fluids. The hospital would code this visit with CPT code 99212 (problem-focused outpatient visit, established patient) and with ICD–9 diagnosis code 460 (acute nasopharyngitis, or common cold). This combination, in turn, would map to APC 911, levels 1 and 2 clinic visit, plus MDC 31, ear, nose, mouth and throat diseases, and payment for this patient's second visit to the hospital clinic would be based on the rate established for hybrid group 91131.

Payment for Screening Services

Every patient who presents to an emergency department and requests (or has requested on his or her behalf) a screening must be screened in accordance with section 1867(a) of the Act. If the physician or other hospital staff who performs the screening determines that no medical emergency exists, the patient can be referred to one of the hospital's clinics or to another provider such as a physician office for further treatment, or the emergency department personnel can decide to treat the patient in the emergency department. We propose to create a HCPCS code to be used to bill the screening. Payment for this new code will be low because no treatment is included in the screening. Payment for the screening APC is made only when no additional services are furnished by the emergency department. If non-emergency treatment is furnished, the appropriate emergency room visit should be billed, and *not* the screening. Similarly, if the screening reveals that an emergency does exist and treatment is instituted immediately, the screening should not be billed; the screening is subsumed into the further treatment. If an emergency room physician feels the need to consult with another physician before deciding whether the patient needs emergency treatment, the consultation is part of the original screening, and the hospital should bill for only one screening visit, if a bill for screening is appropriate, as described above.

Payment for Critical Care

We propose to have hospitals use CPT code 99291 to bill for outpatient encounters in which critical care services are furnished. We use the CPT definition of ''critical care,'' which is the evaluation and management of the unstable critically ill or injured patient who requires the constant attendance of a physician. Under the outpatient PPS, we would allow the hospital to use CPT 99291 in place of, but not in addition to, a code for a medical visit or for an emergency department service. However, the entire duration of the hospital outpatient department's critical care services for an individual patient is represented by CPT 99291, and we would not allow the facility to use CPT 99292 to bill for critical care services extended in 30-minute increments, as would the attending physician. (We have packaged the costs associated with subsequent hours of critical care billing into the APG group of services with which the critical care hours were billed in the base year.) If other services, such as surgery, x-rays, or cardiopulmonary resuscitation, are furnished on the same day as the critical care services, we would allow the hospital to bill for them separately.

We expect that the numbering scheme proposed in this rule to distinguish clinic and emergency room visits would be changed in the final rule. Although we believe the 5-digit identifier used in this proposal makes it easier to see the relationship between the CPT code for the level of the visit and the ICD–9–CM code for the diagnosis, for claims processing purposes, we would have to replace 5-digit identifiers with 3-digit ones.

5. Treatment of Partial Hospitalization Services

In accordance with section 1861(ff) of the Act, partial hospitalization services may be furnished only by a hospital to its outpatients or by a community mental health center (CMHC). We published an interim final rule on February 11, 1994 (59 FR 6570) to establish coverage criteria and payment requirements for partial hospitalization programs. In that rule, we indicated that physician services and certain nonphysician practitioner services are not considered to be partial hospitalization services. Payment for these services is outside the scope of this proposed rule.

The partial hospitalization program of services is organized and furnished similarly, whether the program is administered by a hospital or by a CMHC. Section 1833(a)(2)(B) of the Act requires that payment for CMHC partial hospitalization services be based on the hospital outpatient PPS. Thus, the methodology we are proposing would apply to hospital outpatient and to CMHC partial hospitalization programs. The current rules governing CMHC payment appear in 42 CFR part 413. This proposed rule would amend § 413.1 to indicate that payment for partial hospitalization services furnished by CMHCs is made in accordance with the hospital outpatient prospective payment system described in part 419 of this chapter.

Patients eligible for the Medicare partial hospitalization benefit comprise two groups: patients who have been discharged from a psychiatric hospital for whom partial hospitalization services are provided in lieu of continued inpatient treatment; and patients who exhibit disabling psychiatric/psychological symptoms as a result of an acute exacerbation of a severe and persistent mental illness for whom the partial hospitalization services are provided in lieu of admission to an inpatient psychiatric hospital.

As required by section 1835(a)(2) of the Act, admission to a partial hospitalization program is limited to patients whose physicians certify that: (1) the individual would require inpatient psychiatric care in the absence of partial hospitalization services; (2) an individualized, written plan of care has been established by a physician and is reviewed periodically by a physician; and (3) the patient is or was under the care of a physician. This certification would be made when the physician

believes that the course of the patient's current episode of illness would result in psychiatric hospitalization if the partial hospitalization services are not substituted.

The acute psychiatric condition being treated by a partial hospitalization program must require intensive active treatment, including a combination of medical and nursing interventions, individual and group psychotherapy, occupational therapy, family counseling, and various adjunctive therapeutic activities that are not primarily recreational or diversionary. The patient's degree of impairment must be severe enough to require a multidisciplinary structured day program, but not so severe that patients are incapable of participating in and benefitting from an active treatment program. Patients must require partial hospitalization services at levels of intensity and frequency comparable to patients in an inpatient setting for similar psychiatric illnesses. In addition, the patient must have an adequate community-based network to support the patient outside the partial hospitalization program.

Typically, patients admitted to a partial hospitalization program initially require full-time participation in order to provide crisis stabilization, that is, 6 hours of programming for 5 days per week. In some cases, the patient may ultimately require inpatient psychiatric care despite the partial hospitalization services. However, in most cases, as the patient's symptoms diminish and functional goals are achieved, the frequency of attendance is reduced to 4 days and, later, to 3 days. Once the patient's participation drops to this level, the need for partial hospitalization services in lieu of inpatient psychiatric care is not generally indicated and the patient would be discharged to a lower level of outpatient psychiatric care.

Under the current reasonable cost payment system, providers report the total number of units for each partial hospitalization service furnished during the billing period. As noted earlier, hospitals are also required to report claims for services using HCPCS codes. Payment for the additional overhead cost of supportive staff and recordkeeping for a comprehensive day program of services would be built into the provider's charge structure for covered partial hospitalization services and paid through the cost report settlement process.

Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we believe that a per diem payment for partial hospitalization services is a more appropriate methodology than billing for each component of a partial hospitalization program. A packaged, per diem approach is used by other governmental and private payers when paying for partial hospitalization services. In order to determine the median cost for the partial hospitalization APC group, we analyzed the components reported for each partial hospitalization service over the course of a billing period and established a per diem payment rate. This analysis resulted in an APC payment rate of $208.25 per day, of which $46.78 is the beneficiary's copayment.

As noted above, partial hospitalization providers currently report the total number of units for each service billed. We have revised the billing instructions to require CMHCs to report HCPCS codes and to require hospitals and CMHCs to report the date of each service, effective October 1, 1998. We welcome information from the public to assist us in refining the median cost for a day of partial hospitalization. We are particularly interested in information concerning the mix of services that constitute a typical partial hospitalization day.

We have not established a group to represent a half-day of partial hospitalization, although we are aware that other governmental and private payers have adopted both a full and half-day rate for partial hospitalization. For example, CHAMPUS (Civilian Health and Medical Program of the Uniformed Services) recognizes a day with at least 6 hours of programming as a full day, while days with at least 3 programmed hours, but less than 6, are paid a per diem rate equal to 75 percent of the full day rate. However, the CHAMPUS per diem is not tied to the cost of certain covered services, but rather to the number of programmed hours the patient attends. As noted above, we will begin to collect information October 1, 1998, regarding which services are furnished each day. Once we have analyzed this information, we will be able to determine the extent to which half-days are used typically in partial hospitalization treatment planning. We are interested in public comments regarding whether we should establish a half-day partial hospitalization group.

We have also decided not to propose a minimum number of hours or units of covered services that constitute a partial hospitalization day at this time. However, we are concerned that a low frequency of participation, either very few days per week or few covered services per day, indicate that the partial hospitalization program is no longer reasonable and necessary and the patient could be managed in a less intensive level of outpatient treatment or periodic office visits. Fiscal intermediaries in performing medical review of claims will continue to make decisions regarding whether the services furnished a patient are covered and payable as partial hospitalization services. As noted above, CHAMPUS has established a minimum of 3 hours of service for payment of their partial hospitalization per diem amount. We are specifically requesting public comment on adopting a minimum number of services for Medicare payment purposes.

We note that many other payers have established an annual limit on the number of covered partial hospitalization days. There is currently no duration limit on the Medicare partial hospitalization benefit. Rather, in order to be covered by Medicare, partial hospitalization services must be reasonably expected to improve or maintain the patient's condition and to prevent relapse or hospitalization. For most psychiatric patients, particularly those with long term, chronic conditions, control of symptoms and maintenance of a functional level to avoid hospitalization is an acceptable expectation of improvement. It is not necessary for a course of partial hospitalization services to have, as its goal, restoration of the patient to the level of functioning exhibited prior to the onset of the illness. Some patients may undergo a course of treatment that increases their level of functioning but then reach a point where further significant improvement is not expected. Continued coverage after this point may be dependent upon evidence that the patient is not able to maintain stability with less intensive treatment. Although we are not proposing a duration standard for partial hospitalization at this time, we are concerned that there is significant variation in duration of treatment. We solicit data that show treatment duration from providers of partial hospitalization services. We are also considering specifying a timeframe for periodic physician recertification of need for partial hospitalization services as a method to ensure that a patient's individual needs continue to require the intensity of a partial hospitalization program.

Finally, we are concerned about the impact of establishing a per diem payment for partial hospitalization on the provision of other outpatient mental health services. Patients should be

referred to the outpatient mental health treatment program that best suits their individual needs. Partial hospitalization programs differ from other outpatient mental health treatment programs in the intensity of the program, the frequency of participation, and the patient's need for a comprehensive structured program of services. Upon discharge from a partial hospitalization program, a patient's symptoms and level of functioning will have stabilized to the point that the intensity of a partial hospitalization program is no longer necessary. We are concerned that providing a per diem payment for partial hospitalization services may discourage timely discharge. For this reason, medical review by fiscal intermediaries will continue to focus on patients' initial and continued eligibility for partial hospitalization services.

As noted previously, once we have complete encounter data on which to base the per diem partial hospitalization rate, the per diem will represent the median cost of services furnished on a typical day. As such, it will not be based on the cost of each service furnished on a particular day. Since partial hospitalization represents the most intensive outpatient program and we will have established the median cost of furnishing a day of partial hospitalization services, it does not seem appropriate to pay more for other, less intensive outpatient psychiatric programs. For this reason, we are specifically requesting public comment on establishing a limit on routine outpatient mental health services furnished on a given day to equal the partial hospitalization per diem amount.

6. Comments on Specific APCs

APCs 061–064. We created separate (that is, unpackaged) groups for various chemotherapeutic agents because we believed that some agents had high costs that would not be recognized if those drugs were packaged into the median cost for the chemotherapy administration. We solicit comment on whether to package these costs into the chemotherapy delivery codes in the final rule. We request that commenters identify high-cost chemotherapeutic agents that would not be adequately recognized if packaged or that may require a separate payment or higher payment grouping.

APC 226: This group represents the facility costs for making custom maxillofacial prosthetics. There are few claims, and the median cost is very low compared to the practice expenses associated with these claims on the Medicare physician fee schedule. We assume poor coding accounts for the anomalous cost. However, it may be that these services are not performed in hospital outpatient departments; they may actually be performed by maxillofacial surgeons in their offices or by dental laboratories. We welcome comments on whether these services are actually provided in the outpatient hospital setting and the resources involved.

APC 317 (Cochlear device implantation): The few claims in our database for this procedure have such disparate costs that we are uncertain of the appropriate assignment of the surgery. The device is paid for from the DMEPOS fee schedule. We solicit comments on whether the implant procedure itself resembles procedures in another APC group to which it could be appropriately assigned.

APCs with a status indicator of ''V'': The groups that represent medical visits in clinics and emergency departments are based on a matrix, with intensity represented by six levels of CPT codes combined with 20 categories of ICD–9 codes indicating diagnosis or condition. Although current instructions require hospitals to use a CPT code to bill for medical visits, we permit hospitals to bill for all medical visits under a single code (99201) unless a hospital chooses to be more specific. In 1997, our data show code 99201 accounting for 22 percent of all medical visits billed, which we surmise is an overstatement of the incidence of the lowest level clinic visit. With the implementation of the hospital outpatient PPS, we will require hospitals to begin coding medical visits with greater specificity. As a result, we expect to see an increase in the relative incidence of higher level medical visits and emergency visits and a proportional decrease in the relative incidence of the lowest level clinic visit. We will monitor claims by provider for unexplained increases in the total number of visits or in the proportion of visits billed at the highest levels. Use of HCPCS codes should conform with the CPT clinical examples of cases in each code level.

Because the layout of the outpatient claim form does not allow a HCPCS code to be linked to more than one ICD–9–CM code, the form properly accounts for only one medical visit per claim. When two or more medical visits occur on the same day for different diagnoses, a separate claim would be created for each visit, showing the appropriate level of CPT code and the related diagnosis. We would expect this to occur only in those hospitals that operate many outpatient clinics dedicated to various conditions, such as a diabetes clinic, arthritis clinic, etc. Clinics in which a patient is seen for one or a number of conditions by one health care professional, such as in a primary care clinic, would bill for only one clinic visit for that encounter.

A medical visit would not be billed simply because a patient has presented to a hospital for a service such as chemotherapy, cardiac rehabilitation, an x-ray, etc.

We propose not to pay for a medical visit that takes place on the same date of service as a scheduled outpatient surgery. Registration of the patient, taking of vital signs, insertion of an IV, preparation for surgery, etc., are packaged into and paid for as part of the APC group to which the surgical procedure or service is classified.

In cases where a surgical procedure or service is performed as the immediate result of an outpatient visit (such as the removal of skin lesions following a visit to a dermatology clinic) or from an emergency department visit, the visit would be billed with a modifier −25, indicating that a separately identifiable evaluation and management service was furnished.

APCs 667 and 668: These groups, for cataract surgery without and with insertion of an IOL, should require different resources, because 667 should not include the cost of an IOL. Because the median costs of the two groups are identical, we assume that hospitals were not correctly coding some cases. Therefore, we have reduced the median cost of 667 by $200 to reflect the resources associated with an IOL. We arrived at this figure by allowing the $150 that was allowed for an IOL as the ASC portion of the blended amount formerly paid, and by assuming that the recognition of hospitals' costs under the blend would result in the hospital IOL ''allowance'' being higher than the ASC's. This reduction will have a very small overall effect, because the services in APC 668 were billed more than 225 times as often as those in APC 667. This also leads us to believe that the data we have for the services in APC 668 are more likely to represent accurate information.

APC 670: This group packages payment for the acquisition costs of corneal tissue with the payment for the corneal transplant surgery. It has been brought to our attention that the costs of acquiring corneal tissue vary widely from one locality to another, so that packaging may not be a reasonable way to handle these costs. We are specifically soliciting comments on the issue of packaging corneal tissue costs. We are also soliciting suggestions for alternate ways to pay for corneal tissue, if the comments and supporting data we

receive indicate that packaging is not an appropriate way to treat these costs.

APCs 761 and 762, and 791 and 792: These groups are anomalous, because the group entitled ''Complex'' in each case has a lower weight than the one entitled ''Standard.'' This has to do with the cost of the procedure itself compared to the cost of the radionuclide involved. We are working with the Society for Nuclear Medicine to correct these anomalies.

APCs 902 and 903: We had very few bills for the vaccines in these groups (902 includes polio vaccine and DPT; 903 includes vaccines for rabies and plague). We are considering combining the two groups. We solicit comments on vaccine costs to supplement our data.

APCs 091 and 91191: Brief psychotherapy encounters can be identified by either a CPT code (as in APC 091) or a low- or mid-level visit with a psychiatric diagnosis (APC 91191). We determined the median costs for these bills taken together, because we believe that there are no differences in the facility resources used in these instances. In the case of other psychiatric encounters, we believe that clinic services at the highest level should be the equivalent of an extended psychotherapy encounter. Mid- and high-level emergency room encounters should be billed by evaluation and management CPT codes and psychiatric diagnoses.

APC 921: Although the addenda refer to this APC, in fact diabetic education services will be paid under the physician fee schedule, which will establish rates for one-on-one sessions and group sessions. The addenda will be corrected in the final rule. (A proposed rule titled ''Medicare Program; Expanded Coverage for Diabetes Outpatient Self-Management Training Services'' is under development.)

APCs 981 and 982: These groups represent nerve and muscle tests. We are continuing to evaluate whether these two groups should be combined in the final rule, because there is very little distinction between them in our cost data.

We are still examining ways to pay for drugs outside the composite rate for ESRD patients, and the services to be paid under our system in CORFs, HHAs, and hospices. These will be APCs, based on services that are packaged in our system.

7. Discounting of Surgical Procedures

Under hospital outpatient PPS, we will discount payment amounts when more than one procedure is performed during a single operative session or when a surgical procedure is terminated prior to completion. The discount policy explained below is consistent with Medicare policy and regulations governing payment for physician and ASC surgical services.

a. Reduced Payment for Multiple Procedures

When more than one surgical procedure (defined as those HCPCS codes in APC groups with status ''T'') is performed during a single operative session, we propose that the full Medicare payment amount and beneficiary copayment amount would be paid for the procedure having the highest APC payment rate. Fifty percent of the normal Medicare payment amount and beneficiary copayment amount would be paid for all other procedures performed during the same operative session to reflect the savings associated with having to prepare the patient only once and the incremental costs associated with anesthesia, operating and recovery room use, and other services required for the second and subsequent procedures.

b. Discounted Payment for Terminated Procedures

Under outpatient PPS, the hospital will use modifiers to indicate procedures that are terminated prior to completion. Modifier-52 (Reduced Services) is used to identify a procedure that is terminated after the patient has been prepared for surgery, including sedation when provided, and taken to the room where the procedure is to be performed, but *before* anesthesia is induced (for example, local, regional block(s), or general anesthesia). Fifty percent of the normal Medicare payment amount and beneficiary copayment amount would be paid for a procedure terminated before anesthesia is induced.

Modifier-53 (Discontinued Procedure) is used to indicate that a surgical procedure was started but discontinued *after* the induction of anesthesia (for example, local, regional block, or general anesthesia), or *after* the procedure was started (incision made, intubation begun, scope inserted) due to extenuating circumstances or circumstances that threatened the well-being of the patient. To recognize the costs incurred by the hospital to prepare the patient for surgery and the resources expended in the operating room and recovery room, the full Medicare payment amount and beneficiary copayment amount would be paid for a procedure that was started but discontinued after the induction of anesthesia or after the procedure was started, as indicated by a modifier-53.

The elective cancellation of procedures would not be reported. If multiple procedures were planned, only the procedure actually initiated would be billed. A pattern of canceled procedures will prompt medical review of the reasons for cancellation and may trigger review of the appropriateness of patient selection for outpatient surgery.

8. Inpatient Care

In recent years, the distinction between inpatient and outpatient care has been blurred by the retention of outpatients in the hospital overnight, sometimes for many days in a row. Medicare paid for observation services while the hospital determined whether an outpatient needed admission for further treatment. Frequently, the patients did not understand that they were not inpatients until they were billed for 20 percent of outpatient charges as copayment. In November 1996, we put in place a policy limiting outpatient observation services to a maximum of 48 hours. We made clear at that time that observation was not a means to make it possible to perform inpatient surgery on an outpatient basis, nor was it appropriate to retain chemotherapy patients in long-term observation. Because observation is not provided as the sole service a patient receives, we packaged costs associated with observation into the median costs for the services, for example, surgery or chemotherapy, with which they were furnished in 1996.

There are procedures that, by their nature, require inpatient care. Open abdominal surgery requires a postoperative recovery period, for example, to ensure that bowel function resumes. Certain major surgeries require monitoring in an intensive care unit until the patient's neurological or other function returns. Yet other surgeries involve large or delicate surgical wounds that require monitoring, skilled dressing changes, and fluid replacement. These procedures obviously require inpatient care, and performing them on an outpatient basis would clearly jeopardize patient health and safety. Other procedures are not as clearly defined as inpatient, but we have classified them as inpatient because they are performed on an inpatient basis virtually all the time for the Medicare population, either because of the invasive nature of the procedures, the need for postoperative care, or the underlying physical condition of the patient who would require such surgery. These procedures are not classified in an outpatient APC group, and no payment is provided for these procedures under the hospital

outpatient PPS. We will deny payment for claims that are submitted for these procedures furnished as outpatient services because performing these procedures on an outpatient basis is not safe or appropriate, and therefore not reasonable and necessary under Medicare rules. Because we base these denials on the exclusion in section 1862(a)(1)(A) of the Act and in § 411.15(k)(1), beneficiaries may be protected from liability by the limitation on liability provision of section 1879 of the Act.

The procedures that we consider appropriate and safe only in an inpatient setting and for which we are excluding payment under the hospital outpatient PPS are listed in Addendum H to enable hospitals to make appropriate site of care decisions. This list represents national Medicare policy and is binding on fiscal intermediaries and peer review organizations, as well as on hospitals and Medicare participating ASCs.

We acknowledge that we have classified in outpatient APC groups some procedures that may seem closely related to procedures that we are excluding from the outpatient PPS on the basis of their status as inpatient procedures. We expect that when the former are performed in the outpatient setting, they will be only the simplest, least intense cases. The fact that a service is included in an APC group under the hospital outpatient PPS should not be construed to mean that the procedure may only be performed in an outpatient setting. In every case, we expect the surgeon and the hospital to assess the risk to the individual patient and to act in that patient's best interests.

C. Calculation of Group Weights and Rates

1. Group Weights

Section 1833(t)(2)(C) of the Act requires the Secretary to develop relative payment weights for covered groups of hospital outpatient services. The statute requires that such weights be developed using 1996 hospital outpatient claims and the most recent available hospital cost reports. We are required to base these weights on median hospital costs. In constructing the database to model the outpatient PPS proposal, we used a universe of approximately 98 million calendar year 1996 final action claims for hospital outpatient department services received through June 1997 to match to the most recent hospital cost reports available.

To derive weights based on median hospital costs for services in the hospital outpatient APC groups, we needed to convert billed charges to costs and aggregate them to the procedure or visit level. To do this, we first identified the cost-to-charge ratio that was specific to each hospital's cost centers (''cost center specific cost-to-charge ratios'' or CCRs). We then developed a crosswalk to match the hospital's CCRs to revenue centers used on the hospital's 1996 outpatient bills. The CCRs included operating and capital costs but excluded costs associated with direct graduate medical education and allied health education. (Medicare payment for direct graduate medical education is made as a pass-through under the inpatient PPS and includes the costs associated with approved educational activities for residents assigned to the hospital's outpatient department. We discuss in elsewhere in this proposed rule how we would make payment for allied health education.)

Our next task was to identify each hospital's most recent available cost report from which to determine the hospital's CCRs. Because there is generally a 2-year lag between claims adjudication and cost report filing, the most recent cost reports that we could expect to be available to associate with calendar year 1996 claims were those from PPS–12 (cost reporting periods beginning on or after October 1, 1994 and before October 1, 1995). We searched the PPS–12 period first to match the 1996 final action claims to a cost report. If we achieved a match, no other action was needed. However, if no match was found, we next searched for a cost report in the PPS–11 period and subsequently in the PPS–10 period, if necessary.

If the most recent available cost report that we used for a provider was one that had been submitted but not settled, we calculated an adjustment factor to adjust for the differences that exist between settled and ''as submitted'' cost reports. We determined the adjustment factor by dividing the outpatient department cost-to-charge ratio from the hospital's most recent settled cost report by the outpatient department cost-to-charge ratio from the hospital's ''as submitted'' cost report for the same period. We used the resulting ratio to adjust each of the CCRs in the hospital's most recent ''as submitted'' cost report. We repeated this process for every hospital for which the most recent available cost report was a cost report that had not been settled.

The Office of Inspector General (OIG) is concerned that the cost reports we are using may reflect some unallowable costs. Therefore, the OIG, in conjunction with HCFA, is proposing to examine the extent to which the cost reports used reflect costs that were inappropriately allowed. If this examination reveals excessive inappropriate costs, we would address this issue in a future proposed rule, or perhaps seek legislation to adjust future payment rates downward.

When this process was completed, we were able to match revenue centers from approximately 83 million claims to CCRs of approximately 5,600 hospitals. We excluded from the crosswalk approximately 15 million claims in which the bill type denoted services that would not be covered under the PPS, for example, bill type 72X for dialysis services for patients with ESRD. The table below shows the three cost reporting periods we used and the percentage of the cost reports within each PPS period with which we were able to match 1996 claims. The most recent cost reports available to us were from the hospital inpatient PPS–12 period, and 95.8 percent of the most recent cost reports available to us matched the 1996 claims that we are required to use as the basis for establishing relative payment weights for the APC groups in the outpatient PPS.

Reporting period	Percentage of cost reports matched
PPS–12 (cost reporting period beginning on or after 10/1/94 and before 10/1/95)	95.8
PPS–11 (cost reporting period beginning on or after 10/1/93 and before 10/1/94)	3.7
PPS–10 (cost reporting period beginning on or after 10/1/92 and before 10/1/93)	0.5
	100.0

We next separated the estimated 83 million claims that we had matched with a cost report into two distinct groups: single-procedure claims and multiple-procedure claims. Single-procedure claims are those for which the HCPCS to be grouped to an APC is the only code that appears on the bill, other than laboratory and incidentals such as venipuncture. Multi-procedure claims included more than one HCPCS code that could be mapped to an APC. There were approximately 37 million single-procedure claims and 46 million multiple-procedure claims.

To calculate median costs for services within an APC, we used only the single-procedure bills. (Of the roughly 37 million single-procedure claims, about 11 million were excluded from the conversion process largely because the only HCPCS codes reported on the claims were for laboratory procedures.)

This approach was taken because of our inability to specifically allocate charges or costs for packaged items and services such as anesthesia, recovery room, drugs, or supplies to a particular procedure when more than one significant procedure or medical visit was billed on a claim. Use of the single-procedure bills minimizes the risk of improperly assigning costs to the wrong procedure or visit. Although single-procedure/visit bills were used for determining APC relative payment weights, the multiple-procedure bills were used in the service mix calculations, regressions, and impact analyses.

For each single-procedure claim, we calculated a cost for every billed line item charge by multiplying each revenue center charge by the appropriate hospital-specific CCR. If the appropriate cost center did not exist for a given hospital, we crosswalked the revenue center to a secondary cost center when possible, or to the hospital's overall cost-to-charge ratio for outpatient department services. We excluded from this calculation all charges associated with HCPCS codes previously defined as noncovered under this PPS, for example, laboratory, ambulance, and therapy services.

To calculate the per-procedure or per-visit costs, we used the charges shown in the revenue centers that contained items integral to performing the procedure or visit. These included those items that we previously discussed as being subject to our proposed packaging provision. For example, in calculating the surgical procedure cost, we included charges for the operating room, treatment rooms, recovery, observation, medical and surgical supplies, blood, pharmacy, anesthesia, cast and splints, and donor tissue, bone, and organ. For medical visit cost estimates, we included charges for items such as medical and surgical supplies, drugs, observation, and blood. A complete listing of the revenue centers we used is included elsewhere in this preamble.

To standardize costs for geographic wage variation, we divided the labor-related portion of the operating and capital costs for each billed item by the hospital inpatient prospective payment system wage index published in the **Federal Register** on May 8, 1998 (63 FR 25575). We used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor, but this factor is sensitive to other payment adjustments. Therefore, we will restandardize costs in the final rule using FY 1999 hospital inpatient PPS wage index values and the final labor market share value. A more detailed discussion of wage index adjustments is found below (section V.E. of this document).

We then added the standardized labor-related cost to the non-labor-related cost component for each billed item to derive the total standardized cost for each procedure or medical visit. We trimmed standardized procedure and visit costs to remove extremely unusual costs that appeared to be errors in the data. The trimming methodology is analogous to that used in calculating the DRG weights for the inpatient PPS: any bills with costs outside of 3 standard deviations from the geometric mean were eliminated. The geometric mean and the associated standard deviation are used because the distribution of costs more closely resembles a lognormal distribution than a normal distribution: there are no negative costs, and the average cost is greater than the median cost. Using the geometric mean has the effect of minimizing the impact of the most unusual bills in the determination of the mean. The geometric mean is calculated by taking the mean of the natural logarithm cost. Since the distribution of the natural logarithms of a set of numbers is more compact than the distribution of the numbers themselves, bills with extreme costs do not appear as extreme as they would if non-logged costs were examined. This ensures that only the most unusual data will be removed from the calculation.

After we trimmed the procedure and visit level costs, we mapped each procedure or visit cost to its assigned APC. We calculated the median cost for each APC weighted by procedure volume.

Using these median APC costs, we then calculated the relative payment weights for each APC. We decided to scale all the relative payment weights to APC 91336, a mid-level clinic visit for cardiovascular services because it is one of the most frequently performed services. This approach is consistent with that used in developing relative value units for the Medicare physician fee schedule. By assigning APC 91336 a relative payment weight of ''1.0,'' hospitals can easily compare the relative relationship of one APC to another. Next, we divided the median cost for each APC by the median cost for APC 91336 to derive the relative payment weight for each APC.

2. Conversion Factor

Section 1833(t)(3)(C)(i) of the Act requires that we establish a conversion factor for 1999 to determine the Medicare amounts for each covered group of services. The statute mandates that the conversion factor be established on the basis of the weights and aggregate projected utilization for 1999 and based on the base amount of payments described in section 1833(t)(3)(A) of the Act. Such base amount is calculated for the services included in the outpatient PPS, as an estimate of the sum of (1) total payments that would be payable from the Trust Fund under the current (non-PPS) payment system in 1999 plus (2) the beneficiary copayments that would have been made under the new (PPS) system in 1999. Section 1833(t)(3)(C)(ii) of the Act further requires that the Medicare amount take into account all appropriate adjustments.

Although section 1833(t)(2)(C) of the Act requires us to project utilization for hospital outpatient services, we were unable to project precisely increases in the volume and intensity of services because we were not able to quantify some of the factors that affect utilization. For instance, we would anticipate that Medicare beneficiaries that choose to migrate to managed care plans may be healthier than those who choose to stay in fee-for-service plans. Thus, we could assume a decrease in the volume of services but an increase in the intensity of services furnished for Medicare beneficiaries enrolled in fee-for-service plans. Another factor that we believe will affect future utilization is the incentive to code HCPCS accurately to receive payment. Currently, hospitals are paid for the majority of the outpatient services they furnish on a cost basis. Claims without a HCPCS or an invalid HCPCS are not always rejected. In contrast, under the new PPS, hospitals would be required to use HCPCS codes and, for medical visits and emergency room services, ICD–9 codes, in order to receive payment. We expect that frequencies may increase as a result of the coding requirements. All in all, these are factors we believe will affect the reporting of volume and intensity of services, but we were not able to quantify these assumptions individually to project 1999 utilization. Therefore, we used what we believe to be a more reliable and valid approach to computing the conversion factor under the methodology described below.

Setting the Rates

In order to convert the relative weights determined for each APC (see previous section) into payment rates, we calculated a conversion factor that would result in payments to hospitals under the PPS in 1999 equaling the total projected payment specified in section 1833(t)(3)(A) of the Act. The prospective payment rate set for each APC is

calculated by multiplying the APC's relative weight by a conversion factor. We computed the conversion factor by first adding together for calendar year 1996 the aggregate Medicare hospital outpatient payments paid under the current cost-based payment system (referred to in this section as current law payments) plus the estimated beneficiary copayment amounts that would be paid under the outpatient PPS for the same services. We then divided that amount by the sum of the relative weights for all APCs under the hospital outpatient PPS. The methodology we followed to determine current law Medicare hospital outpatient payments and beneficiary copayments is discussed in section V.C.2.a., below, which is followed in section V.C.2.b. by a discussion of the sum of the relative weights.

a. Calculating Aggregate Calendar Year 1996 Medicare and Beneficiary Payments for Hospital Outpatient Services (Current Law)

First, to calculate Medicare hospital outpatient payment amounts under current law (that is, before PPS), we identified calendar year 1996 single and multiple procedure bills for all the services that we will recognize under the outpatient PPS. As we identified services that will be paid under the outpatient PPS, we eliminated invalid or noncovered HCPCS codes.

Hospital payments include both operating and capital costs for the HCPCS coded services for which payment is to be made under the outpatient PPS. We summed both of these types of costs by HCPCS at the provider level. Summarizing the data in this manner allows us to simulate provider payment on an aggregate basis. We then applied the legislated capital cost reductions of 10 percent and operating cost reductions of 5.8 percent, as required by section 4522 of the BBA.

We determined for each HCPCS code the applicable payment methodology under current law. We then calculated current law payment for procedures in the baseline using one of the following equations, as appropriate:

- For radiology procedures paid for under the radiology fee schedule, payment is determined in the aggregate for each provider as the lower of cost, charge, or blended amount. The radiology blended amount is determined by the following equation:

(0.42 × lower of cost or charge minus beneficiary copayment) + (0.58 × ((0.62 × global physician fee schedule amount) − beneficiary copayment))

- For surgical procedures for which Medicare pays an ASC facility fee, payment is determined in the aggregate for each provider as the lower of the cost, charge, or blended amount. The ASC blended amount is determined by the following equation:

(0.42 × lower of cost or charge minus beneficiary copayment) + (0.58 × (ASC payment rate − beneficiary copayment))

- For diagnostic procedures paid under the diagnostic fee schedule, payment is determined in the aggregate for each provider as the lower of cost, charge, or blended amount. The blended amount is determined by the following equation:

(0.50 × lower of cost or charge minus beneficiary copayment) + (0.50 × ((0.42 × global physician fee schedule amount) − beneficiary copayment))

For all other covered services not subject to one of the blended payment method categories, payment is determined to be the lower of costs or charges less beneficiary copayment. Because the formula-driven overpayment (FDO) was corrected beginning October 1, 1997, the blended equations eliminate FDO.

We then determined each provider payment. We summed the aggregate amounts computed for each of the four types of payment methodologies discussed above to determine the Medicare payment amount for each provider. In addition, we also determined the amount of the beneficiary copayment for each provider using the beneficiary copayment amounts that would be paid under the PPS. Summing both the Medicare payment and the beneficiary copayment amounts at the provider level is necessary in order to determine the impact of the outpatient PPS on individual hospitals. In addition to calculating provider payments under the current law and PPS payment systems, we calculated the aggregate Medicare payments under the current system and beneficiary copayments under the PPS for all hospitals for services that are within the scope of the outpatient PPS. The total amount reflects the amount hospitals would be paid under the PPS in accordance with section 1833(t)(3)(A) of the Act and is the numerator in the equation for calculating the unadjusted conversion factor.

b. Sum of the Relative Weights

Next we summed the relative weights. Specifically, we multiplied the volume of procedures or visits (excluding the volume of packaged services) for each group by the relative weights for each group. We then calculated the conversion factor by dividing the sum of the volume multiplied by the relative weights for each APC into the total payment explained above, including both Medicare payment and beneficiary copayment. The calendar year 1996 conversion factor is $46.32. To trend forward the 1996 conversion factor to 1999, HCFA's Office of the Actuary estimated an update factor of 1.0939. The update factor represents the estimated per service increase in outpatient Medicare payments and beneficiary copayment between 1996 and 1999 net of changes in the volume and intensity of services. Medicare payments per service were increased by projected CPI-medical items for cost-based services and for blend services mandated updates. Beneficiary copayments were increased by projected increases in CPI-outpatient charges. In estimating the update factor, HCFA's Office of the Actuary assumed that using the national median of the charges for PPS services to establish the unadjusted copayment amount would result in beneficiaries paying 6.9 percent less in coinsurance payments in 1999 than what they would have been expected to pay otherwise, which would create an incentive for a behavioral offset by hospitals of 10 percent of the coinsurance reduction. It was assumed that 45 percent of this offset would apply to the services subject to the PPS and, therefore, would be included in setting the 1999 conversion factor. The remaining 55 percent of the offset would be reflected in expenditures for non-PPS services with both the beneficiary and Medicare absorbing this impact. The adjusted 1999 conversion factor is $50.67.

D. Calculation of Medicare Payment Amount and Copayment Amount

1. Introduction

In the previous section, section V.C, we explain how we determined national prospective payment rates, standardized for area wage variations, for the APC groups. In this section, we explain how we are proposing to calculate Medicare program payment amounts and beneficiary copayment amounts for each APC group.

Under the statutory provision currently in effect, copayment for hospital outpatient department services is based on 20 percent of the hospital's billed charges. Because most hospital outpatient services have been paid, at least in part, on the basis of retrospectively calculated cost, Medicare payment amounts for most

hospital outpatient services are not known at the time the services are furnished. For that reason, coinsurance could not be based on 20 percent of the payment amount. Accordingly, the statute required that copayment be based on 20 percent of charges. Because charges for hospital outpatient services have increased faster than costs for those services, beneficiaries' copayments of 20 percent of charges have, for some services, accounted for 50 percent or more of the total (Medicare program plus beneficiary) payments to the hospitals. Because of extensive secondary insurance coverage, a large share of the copayments made to hospitals is not direct out-of-pocket expenditures by the beneficiaries. There has, however, been concern that premiums for Medigap policies may be affected by the growing copayment liability. In addition, copayments most directly affect those beneficiaries who do not have supplemental insurance. This group of beneficiaries cannot afford to purchase supplemental insurance, and high copayment rates can be a hardship for those needing services. The outpatient PPS created by section 4523 of the BBA, which added section 1833(t) to the Act, includes a mechanism that is designed to eventually achieve a beneficiary copayment level equal to 20 percent of the prospectively determined payment rate that has been established for the service.

MedPAC Comment: In its March 1998 report to the Congress, MedPAC expresses concern about the inequity represented by the current level of beneficiary copayment liability, which generally exceeds 20 percent of the total payment to hospitals for outpatient services. MedPAC, recognizing that immediate beneficiary copayment reductions to 20 percent of payments made to hospitals would result either in unacceptable increases in program outlays and/or unacceptable reductions in payments to hospitals, agrees with the need for a phased-in approach to the copayment reductions. However, MedPAC recommends that the Congress specify a shorter timeframe than that which results from the provisions of the BBA to phase in fully the appropriate beneficiary copayment contribution of 20 percent for hospital outpatient services paid for under the outpatient PPS.

Response: While we do not disagree with MedPAC's recommendation with respect to beneficiary copayment, because of the budgetary implications and the existing statutory requirements resulting from the BBA, implementation of this recommendation would ultimately require action by the Congress.

The next sections describe the steps that we followed in accordance with statutory requirements to determine the beneficiary copayment amount and the Medicare program payment amount for services paid for under the hospital outpatient PPS.

2. Determination of Unadjusted Copayment Amount, Program Payment Percentage, and Copayment Percentage

In order to calculate program payment amounts and beneficiary copayment amounts, we first determined for each APC group two base amounts, in accordance with statutory provisions:

- An *unadjusted copayment amount*, described in section 1833(t)(3)(B) of the Act.
- The ''pre-deductible payment percentage,'' which we call *the program payment percentage*, described in section 1833(t)(3)(E).

The steps that we followed to calculate these two base amounts for each APC group are explained below.

(a) *Calculate the unadjusted copayment amount for each APC group.*

(i) Determine the national median of the charges billed in 1996 for the services that constitute the APC group after standardizing charges for geographic variations attributable to labor costs. (To make the labor adjustment, we divided the portion of each charge that we estimated was attributable to labor costs (60 percent) by the provider's hospital inpatient wage index value, and we added the result to the non-labor portion of the charge (40 percent). Section V.F. provides a detailed discussion of the adjustments made within the outpatient PPS to offset regional differences in labor costs.)

(ii) Update charge values to projected 1999 levels by multiplying the 1996 median charge for the APC group by 29.2 percent, which the HCFA Office of the Actuary estimates to be the rate of growth of charges between 1996 and 1999.

(iii) Multiply the estimated 1999 national median charge for the APC group by 20 percent, which becomes the *unadjusted copayment amount* for the APC group. The *unadjusted copayment amount* is frozen at the 1999 level until such time as the program payment percentage (see below) equals or exceeds 80 percent (section 1833(t)(3)(B)(ii) of the Act).

(b) *Calculate the program payment percentage (pre-deductible payment percentage).* In this proposed rule, we use the term *program payment percentage* to replace the term ''pre-deductible payment percentage,'' which is referred to in section 1833(t)(3)(E) of the Act. The *program payment percentage* is calculated annually for each APC group, until the value of the program payment percentage equals 80 percent. To determine the program payment percentage for each APC group, we followed these steps:

(i) Subtract the APC group's unadjusted copayment amount from the payment rate set for the APC group;

(ii) Divide the difference [(APC payment rate) minus (unadjusted copayment amount)] by the APC payment rate, and multiply by 100. The resulting percentage is the program payment percentage.

Calculation of the program payment percentage allows us to determine a ''copayment percentage,'' which equals the difference between the program payment percentage and 100 percent. As the program payment percentage for an APC group approaches 80 percent due to annual market basket increases of the APC payment rates, the copayment percentage, conversely, approaches 20 percent, which is ultimately the target copayment percentage for all services paid for under the hospital outpatient PPS. When the copayment percentage equals 20 percent of the APC payment rate, we consider the copayment amount for that APC to be fully phased in at the standard Medicare copayment level, as we explain in the next section.

3. Calculation of Medicare Payment Amount and Beneficiary Copayment Amount

a. *Calculate the Medicare payment amount.* A Medicare payment amount is calculated for every APC group. The Medicare payment amount takes into account wage index and other applicable adjustments and applicable beneficiary deductible amounts. The Medicare payment amount calculated for an APC group applies to all the services that are classified within that APC group. The Medicare payment amount for a specific service classified to an APC group under the outpatient PPS is calculated as follows:

(i) Apply to the national payment rate that is set annually for each APC group the appropriate wage index adjustment (see section V.E. for a discussion of how national APC rates are to be adjusted for geographic wage differences) and any other adjustments applicable to the provider;

(ii) Subtract from the adjusted APC group payment rate the amount of any applicable deductible as provided under § 410.160; and

(iii) Multiply the adjusted APC group payment rate, from which the applicable

deductible has been subtracted, by the program payment percentage determined for the APC group or 80 percent, whichever is lower. The result is the Medicare payment amount.

b. *Calculate the copayment amount.*

A *copayment amount* is calculated annually for each APC group. The copayment amount calculated for an APC group applies to all the services that are classified within the APC group. The copayment amount for an APC is calculated as follows:

Subtract the APC group's Medicare payment amount from the adjusted APC group payment rate less deductible, for example, COPAYMENT AMOUNT *equals* [(adjusted APC group payment rate less deductible) *minus* (APC group Medicare payment amount). The resulting difference is the beneficiary copayment amount.

Again, as soon as the Medicare program payment percentage of an adjusted APC payment rate less deductible equals or exceeds 80 percent, we set the copayment amount at 20 percent of the adjusted APC group payment rate, and we consider the standard Medicare 20 percent copayment level to be fully phased in for that APC group (section 1833(t)(3)(B)(ii) of the Act). Thereafter, for those APC groups whose program payment percentage has become 80 percent of the APC payment rate (and whose copayment percentage is 20 percent), the unadjusted copayment amount for the APC ceases to be frozen at the 1999 level. The copayment amount for the APC group is permanently established at 20 percent of the adjusted APC group payment rate. Because the copayment amount is now tied directly to the APC payment rate, the copayment dollar amount increases as annual updates increase the APC group payment rate.

For example, assume that the wage-adjusted payment rate for an APC is $300; the program payment percentage for the APC group is 60 percent; the wage-adjusted copayment amount for the APC group is $120; and the beneficiary has not yet satisfied any portion of his or her annual $100 deductible.

(A) Adjusted APC payment rate: $300
(B) Subtract the applicable deductible: $300 − $100 = $200
(C) Multiply the remainder by the program payment percentage to determine the Medicare payment amount: 0.6 × $200 = $120
(D) Subtract the Medicare payment amount from the adjusted APC payment rate less deductible to determine the copayment amount: $200 − $120 = $80

In this case, the beneficiary pays a deductible of $100 and an $80 copayment. The program also pays $120, for a total payment to the hospital of $300. Applying the program payment percentage ensures that the program and the beneficiary pay the same proportion of payment that they would have paid if no deductible were taken.

In the event that the annual deductible has already been satisfied, the calculation runs as follows:

(A) Adjusted APC payment rate: $300
(B) Subtract the applicable deductible: N/A
(C) Multiply by the program payment percentage to determine the Medicare payment amount: 0.6 × $300 = $180
(D) Subtract the Medicare payment amount from the adjusted APC payment rate less deductible to determine the copayment amount: $300 − $180 = $120

In this case, the beneficiary makes a $120 copayment. The program also pays $180, for a total payment to the hospital of $300.

4. Hospital Election To Offer Reduced Copayment

The transition to the standard Medicare copayment rate (20 percent of the wage-adjusted APC payment rate) will obviously be gradual. For those APC groups for which copayment is currently a relatively high proportion of the total payment, the process will be correspondingly lengthy. Therefore, the Act offers hospitals the option of electing to reduce copayment amounts and allows the hospital to advertise these reduced rates. In this section, we discuss the procedure by which hospitals can elect to offer a reduced copayment amount, and the effect of such election on calculation of the program payment and beneficiary copayment.

Section 1833(t)(5)(B) of the Act requires the Secretary to establish a procedure under which a hospital, before the beginning of a year, may elect to reduce the copayment amount otherwise established for some or all hospital outpatient department services to an amount that is not less than 20 percent of the hospital outpatient prospective payment amount. The statute further provides that the election of a reduced copayment amount will apply without change for the entire year, and that the hospital may advertise its reduced copayment levels. Section 1833(t)(5)(C) of the Act provides that deductibles cannot be waived. Finally, section 1861(v)(1)(T) of the Act (as established by section 4451 of the BBA) provides that no reduction in copayment elected by the hospital under section 1833(t)(5)(B) may be treated as a bad debt.

In this rule, we are proposing that a hospital may make the election to reduce copayments on a calendar year basis. The hospital must notify its fiscal intermediary of its election to reduce copayments no later than 90 days prior to the start of the calendar year. This 90-day notification requirement is necessary in order to give the intermediaries sufficient time to make the systems changes required to implement the hospital's election. The hospital's notification must be in writing. It must specifically identify the APC groups to which the hospital's election will apply and the copayment level (within the limits identified below) that the hospital has selected for each group. The election of reduced copayment must remain in effect unchanged during the year for which the election was made. The hospital may advertise and otherwise disseminate information concerning the reduced level of copayment that it has elected.

We also are proposing that a hospital may elect to reduce the copayment amount for any or all APC groups. A hospital may *not* elect to reduce the copayment amount for some, but not all, services within the same APC group.

A hospital may not elect for an APC group a copayment amount that is less than 20 percent of the adjusted APC payment rate for that hospital. In determining whether to make such an election, hospitals should note that the national copayment amount under this system, based on 20 percent of national median charges for each APC, may yield copayment amounts that are significantly higher or lower than the copayment that the hospital has previously collected. This is because the median of the national charges for an APC group, from which the copayment amount is ultimately derived, may be higher or lower than the hospital's historic charges. We, therefore, advise that hospitals, in determining whether to exercise the option of electing lower copayment and the level at which to make the election, carefully study the annual copayment amounts for each APC group in relation to the copayment amount that the hospital has previously collected.

Calculation of copayment amounts on the basis of a hospital's election of reduced copayment for the most part follows the formula described previously. For example, assume that the adjusted APC payment rate is $300; the program payment percentage for the

APC group is 60 percent; the hospital has elected a $60 adjusted *reduced* copayment amount for the APC group; and the beneficiary has not satisfied the annual deductible.

(A) Adjusted APC payment rate: $300
(B) Subtract the applicable deductible: $300 − $100 = $200
(C) Multiply by the program payment percentage to determine the Medicare payment amount: 0.6 × $200 = $120
(D) Beneficiary's copayment is the difference between the APC payment rate reduced by any deductible amount and the Medicare payment amount, but not to exceed the adjusted reduced copayment amount: $200 − $120 = $80 (limited to $60 because of the hospital-elected reduced copayment amount)

In this case, Medicare makes its regular payment of $120, but the beneficiary pays a $100 deductible and a reduced copayment amount of $60, for a total payment to the hospital of $280 instead of the $300 that the hospital would have received if it had not made its election.

E. Adjustment for Area Wage Differences

1. Proposed Wage Index

Section 1833(t)(2)(D) of the Act requires that, as part of the methodology for determining prospective payments to hospitals for outpatient services, the Secretary must determine a wage adjustment factor to adjust the portion of payment and copayment attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget-neutral manner.

To determine which wage adjustment factor to incorporate into the hospital outpatient department PPS, we considered several options. One choice would be to use a wage index specific to hospital outpatient department labor costs. However, the Congress did not require us to nor did we have either the time or resources necessary to construct a hospital-outpatient-department-specific wage index.

We next considered the hospital inpatient PPS wage index that HCFA maintains under the Medicare program. The hospital inpatient PPS wage index is well established, and it is constructed specifically for the purpose of ''reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level'' (section 1886(d)(3)(E) of the Act), a requirement that is analogous to that set forth under the hospital outpatient department PPS in section 1833(t)(2)(D) of the Act. The data upon which the hospital inpatient PPS wage index is based are collected from Medicare cost reports, and the wage index is updated annually. Any changes in hospital inpatient PPS wage index values must be made in such a manner as to assure budget neutrality (section 1886(d)(3)(E) of the Act). The hospital inpatient PPS wage index for fiscal year 1998 reflects the following:

- Total salaries and hours from short-term, acute care hospitals.
- Home office costs and hours.
- Fringe benefits associated with hospital and home office salaries.
- Direct patient care contract labor costs and hours.
- The exclusion of salaries and hours for nonhospital type services such as SNF services, home health services, or other subprovider components that are not subject to the PPS.

A detailed description of the fiscal year 1999 hospital inpatient PPS wage index is contained in the proposed rule entitled ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates (HCFA–1003–P)'' published in the **Federal Register** on May 8, 1998 (63 FR 25575).

We decided that using the hospital inpatient PPS wage index as the source of an adjustment factor for geographic wage differences for the hospital outpatient department PPS was both reasonable and logical, given the inseparable, subordinate status of the outpatient department within the hospital overall. We then had to determine which version of the hospital inpatient PPS wage index to use. There are several possible wage indices that can be developed from the basic wage and salary data taken from hospital cost reports, depending on changes that are applied to the data. One modification takes into account the effect of hospital redesignation under 1886(d)(8)(B) of the Act and hospital reclassification under 1886(d)(10). A second modification results from assigning to an urban hospital the statewide rural wage index value for the State in which that hospital is located when the wage index of the urban hospital would otherwise be lower than the statewide rural wage index value (the ''floor''). (In fiscal year 1998, this particular ''hold harmless'' provision affected 128 hospitals in 32 metropolitan statistical areas (MSAs).) Given the choice between the wage index that we use under the hospital inpatient PPS, which reflects reclassification and other changes, and a wage index that does not incorporate these changes, we are proposing to adopt the wage index that is used to determine payments to hospitals under the hospital inpatient PPS to adjust for relative differences in labor and labor-related costs across geographic areas under the hospital outpatient department PPS. We note that hospital outpatient department services do not fall under the category of either ''nonhospital type services'' or of ''other subprovider components,'' which are excluded from consideration in developing the hospital inpatient PPS wage index. We also note that because hospital staff frequently provide services in both the inpatient and outpatient departments, labor costs associated with hospital outpatient department services are generally reflected in the hospital wage and salary data that are the basis of the hospital inpatient PPS wage index.

By statute, we implement the annual updates of the hospital inpatient PPS on a fiscal year basis. However, updates to the hospital outpatient department PPS will be made on a calendar year basis. We are proposing to update the wage index values used to calculate hospital outpatient department PPS Medicare payment and beneficiary copayment amounts on a calendar year basis. In other words, the hospital inpatient PPS wage index values that are updated annually on October 1 will be implemented for the hospital outpatient department PPS on the January 1 immediately following. We are proposing this schedule so that wage index changes are implemented concurrently with any other revisions, such as changes in the APC groups resulting from new or deleted CPT codes, that are implemented on a calendar year basis.

2. Labor-Related Portion of Hospital Outpatient Department PPS Payment Rates

In calculating payments to hospitals under the hospital inpatient PPS, the labor-related portion of expenses within the standardized amounts used to establish the prospective payment rates is multiplied by the hospital wage index value to offset regional wage differences. The fiscal year 1998 labor-related portion under the hospital inpatient PPS is 71.1 percent. The manner in which this portion was calculated is explained in detail in the August 29, 1997 **Federal Register** (62 FR 45993). We note that compensation for wages, salaries, and employee benefits accounts for 61.4 percent of expenses, with the other 9.7 percent attributable to professional fees, postal services, and all other labor-intensive services, as explained in the August 29, 1997 **Federal Register** (62 FR 45995).

Current ASC payment rates are standardized for regional wage differences, and carriers adjust the base rates to calculate payments to individual facilities by multiplying the labor-related portion of the base rate by the appropriate hospital inpatient PPS wage index factor. The labor-related portion of current ASC payment rates is 34.45 percent based on 1986 ASC survey data.

Because of the sequence of steps that we followed to construct the hospital outpatient department services PPS database, we had to estimate the percentage of hospital outpatient department costs attributable to labor in order to standardize hospital outpatient department costs for geographic wage differences. We decided that 60 percent represented a reasonable estimate of outpatient costs attributable to labor, as it falls between the hospital inpatient PPS operating cost labor factor of 71.1 percent and the ASC labor factor of 34.45 percent and is within a percentage point of the labor-related costs under the hospital inpatient operating cost PPS attributed directly to wages, salaries, and employee benefits (61.4 percent) under the rebased 1992 hospital market basket that was used to develop the fiscal year 1997 update factor for inpatient PPS rates (published August 30, 1996 at 61 FR 46187). In addition to considering what percentage of costs is attributed to labor by other payment systems, we considered health care market factors such as the shift of more complex services from the inpatient to the outpatient setting, which could influence labor intensity and costs, and 60 percent seemed appropriate. (As we explain in section V.I. below, regression analysis confirmed the labor percentage to be 60 percent.) We calculated 60 percent of each hospital's total operating and capital costs. We then divided that amount by the provider's 1996 hospital inpatient PPS wage index value to standardize differences in costs that are attributable to geographic wage differences. The total cost of performing a procedure/visit, therefore, includes wage-standardized operating and capital costs, as well as bundled ancillary costs (that is, operating room time, medical/surgical supplies, pharmaceuticals, anesthesia, recovery room, observation, biologicals, etc.) and minor ancillary procedures (for example, venipuncture), as explained in greater detail in section V.C.

The final hospital outpatient department PPS payment rates that would have been effective January 1, 1999 may differ slightly from those proposed in this rule because we intend to adjust APC payment rates using the fiscal year 1999 hospital inpatient PPS wage index values that are implemented October 1, 1998. The hospital inpatient PPS wage index values proposed for fiscal year 1999 are in the **Federal Register** proposed rule published May 8, 1998 entitled ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates (HCFA–1003–P)'' (63 FR 25575).

We are proposing to use the annually updated hospital inpatient PPS wage index values to adjust both program payment and copayment amounts for area wage variations, as we explain below.

3. Adjustment of Hospital Outpatient Department PPS Payment and Copayment Amounts for Geographic Wage Variations

To adjust the APC payment rates and beneficiary copayment rates for outpatient services for geographic wage variations, we are proposing to use the same labor-related percentage (60 percent) that we used initially to standardize costs for geographic wage differences. When intermediaries calculate actual payment amounts, they will multiply the prospectively determined APC payment rate and copayment amount by that labor-related percentage to determine the labor-related portion of the base payment and copayment rates that is to be adjusted using the appropriate wage index factor. That labor-related portion will then be multiplied by the hospital's inpatient PPS wage index factor, and the resulting wage-adjusted labor-related portion will be added to the non-labor-related portion, resulting in wage-adjusted payment and copayment rates. The wage-adjusted copayment amount is then subtracted from the wage-adjusted APC payment rate, and the result is the Medicare payment amount for the service or procedure. Note that even if a hospital elects to discount the copayment, the full copayment amount is assumed for purposes of determining Medicare program payments. (See section V.D. for a discussion of how Medicare program payments are calculated when the Part B deductible applies.)

The following is an example of how an intermediary would calculate the Medicare payment for a surgical procedure with a hypothetical APC payment rate of $300 that is performed in the outpatient department of a hospital located in Heartland, USA. The copayment amount for the procedure is $105. The hospital inpatient PPS wage index value for hospitals located in Heartland, USA is 1.0234. The labor-related portion of the base payment rate is $180 ($300 × 60 percent), and the non-labor-related portion of the base payment rate is $120 ($300 × 40 percent). The labor-related portion of the base copayment rate is $72 ($120 × 60 percent), and the non-labor-related portion of the base copayment rate is $48 ($120 × 40 percent). It is assumed that the beneficiary deductible has been met.

Wage-Adjusted Base Payment Rate (rounded to nearest dollar):
= ($180 × 1.0234) + $120
= $184 + $120
= $304

Wage-Adjusted Base Copayment Rate (rounded to nearest dollar):
= ($72 × 1.0234) + $48
= $74 + $48
= $122

Calculate Medicare Program Payment Amount:
$304 − $122 = $182

F. Claims Submission and Processing

Hospitals will receive detailed instructions on claims submission over the coming year. This section provides a brief overview of the process.

In order for APCs to properly capture services furnished, hospitals must assign HCPCS codes to services. Revenue center codes will capture only packaged services (operating and recovery room, pharmaceuticals, medical/surgical supplies, etc.). Correct assignment of codes requires an understanding of the differences among surgical procedures, a knowledge of the extent of effort expended in a clinic visit, etc. We believe that many hospitals currently have surgical records coded using HCPCS in the medical records department. However, many hospital coders are much more familiar with the ICD–9–CM system of classification than they are with HCPCS. Among the sources of education available to update skills, hospitals may want to explore in-service education from a credentialed coder with experience in billing for physicians' and surgeons' services, classes available from local hospital associations or medical record associations, formal classes in local colleges, etc.

Coding conventions in the outpatient setting differ slightly from those in use in inpatient settings. The diagnosis identified on the claim need not be the ''principal'' diagnosis, as required under DRGs. Instead the diagnosis is the reason for the visit as identified at the time of the visit. It is not necessary to wait to submit the claim until laboratory or x-ray results are known, in an effort to more clearly identify the diagnosis. In billing for clinic and emergency

department visits, the diagnosis should relate to the reason for the visit. A patient who attends several different clinics in one day should have separate claims submitted for each clinic visit, since at this time only one diagnosis can be associated with each claim. We will seek a change to the UB–92 allowing diagnoses to be identified by number, so that each line item can have a diagnosis associated with it.

Another difference from inpatient reporting is that the DRG GROUPER can take every procedure coded and identify the one highest in the surgical hierarchy applicable to the diagnosis, then ignore those that do not affect the DRG. The HCPCS codes, however, are both more numerous and very specific and should be used appropriately, since each code will trigger a payment.

We propose to apply to hospital outpatient claims HCFA's Correct Coding Initiative (CCI). One of the purposes of the CCI is to ensure that the most comprehensive of a group of codes is billed instead of the component parts. For example, G0001 (routine venipuncture) is a component part of 36430 (transfusion of blood or blood components) and should not be separately billed. Similarly, 94760 (pulse oximetry) should not be billed with surgical procedures for which it is a common monitoring technique. In 1997, hospital outpatient claims showed it more than 10,000 times with 45378 (diagnostic colonoscopy). The CCI also checks for mutually-exclusive code pairs. For example, 93797 (cardiac rehabilitation without ECG monitoring) should not be billed simultaneously with 93798 (cardiac rehabilitation with ECG monitoring), which happened nearly 12,000 times in 1997 hospital outpatient claims. We propose to use the CCI edits to ensure that only appropriate codes are grouped and priced.

Carriers have used CCI as an editing tool since January 1996, and have discovered that the vast majority of edits are rarely triggered. However, as shown in the examples above, hospitals' coding patterns could result in inappropriate payments unless such edits are applied. Under the cost reimbursement system, these types of errors did not ultimately result in higher payments to the hospitals; nor did providing wrong numbers in the units field (for example, repeating the revenue code). Again, under this PPS, each unit billed will trigger a payment. Thus, we have created a second set of edits limiting the number of units allowed for each HCPCS code. For example, only ''1'' will be accepted in the units field for cataract surgery, but for most services the edit allows for the procedure to be performed a number of times in a day, with an upper limit to reduce obvious errors. Of course, hospitals should report only the actual number of times a procedure was performed, keeping in mind that CPT and HCPCS definitions sometimes specify the units. For example, code 11720 is for debridement of nail(s) by any method; one to five. This code should be reported only once for any number of nails debrided between one and five, inclusive. If more than five nails are debrided, the appropriate code is 11721, debridement of nail(s) by any method; six or more, billed only once in place of 11720.

We propose to require that hospital outpatient and CMHC bills that span more than one day indicate the date of the service for each line item on the bill. Line item dates of service are needed in order to implement the CCI and the units' edits, both of which are applied based on services furnished on the same date.

Further information on billing line item dates of service, using HCPCS to code all claims, and editing will be provided by instructions.

G. Updates

1. Revisions to Weights and the Wage and Other Adjustments

Section 1833(t)(6)(A) of the Act gives the Secretary authority to periodically review and update the APC groups, the relative payment weights, and the wage and the other adjustments that are components of the outpatient PPS, to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

We explained above that we intend to update the wage index values used to calculate program payment and copayment amounts on a calendar year basis, adopting effective for services furnished each January 1 the wage index value established for a hospital under the inpatient PPS the previous October 1.

Recalibration of the APC group weights is another type of revision provided for under the statutory review authority. We define recalibration as the updating of all the APC group weights based on more recent information. We do not intend to make this type of update on an annual basis. For example, we are required to rebase ASC payment rates using survey data that are collected every 5 years. At this time, we would like to solicit comments on how frequently to recalibrate the hospital outpatient APC weights and on the method and data that should be used.

Section 1833(t)(6)(B) of the Act requires that all revisions to APC groupings, weights, and other adjustments be made in a budget-neutral manner. Adjustments made for a particular year may not cause the estimated amount of expenditures under the outpatient PPS to increase or decrease from the expenditures that we estimate would have been made under the outpatient PPS without any updates or revisions.

2. Revisions to APC Groups

It is our intent to use the same APC surgical groups in the payment systems both for hospital outpatient services and for surgical services furnished by Medicare-approved ASCs. A discussion of the use of APC groups to set payment rates for Medicare-approved ASCs can be found in the proposed rule entitled ''Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998'' (HCFA–1885–P) that was published in the **Federal Register** June 12, 1998 (63 FR 32290). In order to maintain comparability of the APC groups across both settings, we are proposing to coordinate our review of comments on the composition of the APC groups that are submitted during the public comment period following publication of both this proposed rule and the ASC proposed rule. We are further proposing to coordinate any adjustments to the composition of the APC surgical groups that may result from our analysis of both sets of comments to ensure that the final APC surgical groups not only reflect and take into account both sets of comments, but also remain comparable for ASCs and hospital outpatient departments to the maximum extent possible within the constraints imposed by statutory and regulatory requirements.

Thereafter, we expect the composition of all the APC groups to remain essentially intact from one year to the next with the exception of the few changes that may be necessary as a consequence of annual revisions to HCPCS and ICD–9 codes. We do not plan to routinely reclassify services and procedures from one APC to another. HCFA will make these changes based on evidence that a reassignment would improve the group(s) either clinically or with respect to resource consumption. All changes in APC groups must be budget neutral, and changes in APC groups will only be made through notice and comment when we implement the annual outpatient PPS update.

We are proposing to follow certain conventions when, as a result of annual HCPCS and ICD–9 revisions, we add new services to the hospital outpatient PPS. As part of the notice and comment process accompanying the annual update of the outpatient PPS, we shall propose the assignment of a newly created code to the existing APC that, in the judgment of our medical advisors, is the most similar clinically and in terms of resource requirements to the new service. Because a new service will not have any charge history or cost data associated with it, classification of a new service to an existing APC group will not alter the APC payment rate, relative weight, and program payment and copayment amounts that have been established for that APC group. The new service will assume the same payment rate, relative weight, and program and copayment amounts that have been established for the APC group to which it is classified.

If the annual revision of HCPCS or ICD–9 result in the deletion of a code or service that is classified in an APC group under the outpatient PPS, we shall remove that service from the APC group and discontinue paying for the service under the outpatient PPS. When a CPT code that contributed cost data to our 1996 database is deleted, we will continue to use the cost data in the APC. This in fact did occur in the psychotherapy set of codes. The codes that were in effect in 1996 have been replaced. If we did not capture these data from those codes, we would not be able to assign a weight to brief psychotherapy visits. As long as the new codes belong in the same APC, in terms of clinical coherence and related resource use, the data are relevant. If the code that contributed data to the 1996 database were revised so that it no longer belonged in the APC to which it was originally assigned, the revised code would be placed in an APC that better matched the new description. As in the case of an entirely new code, no cost data would be available for the revised code, so it would be assigned the weight, program payment rate, and copayment rate of the codes in the new APC. We will not create an APC for an entirely new code, but will assign it for at least 2 years to an existing group while accumulating data on its costs relative to the other codes in the APC.

When we do reclassify a service from one APC group to another, the reclassification will affect the payment rate, the weight, and the payment and copayment amounts for both of the ''donor'' APC group and the ''receiving'' APC group if the service that is reclassified was recognized in 1996 and is reflected in our database. As a result of reclassifying a service that was recognized in 1996 and is reflected in our database, we shall recalculate the payment rate, the weight, and the payment and copayment amounts for both the ''donor'' APC group and the APC group to which the service is reassigned. If the service that is reclassified was not recognized in 1996 and is therefore not reflected in our database, we shall treat it in the same manner that we treat the addition of altogether new services and the removal of services that are deleted from HCPCS and ICD–9, that is, reclassifying the code will have no effect on the payment rate, relative weight, and payment and copayment amounts for either the donor APC or the receiving APC, and the reclassified code will assume the payment rate, relative weight, and payment and copayment amounts of the APC to which the service is reclassified.

3. Annual Update to Conversion Factor

Section 1833(t)(3)(C)(ii) of the Act requires us to update annually the conversion factor used to determine APC payment rates. Section 1833(t)(3)(C)(iii) of the Act provides that the update be equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act, reduced by one percentage point for the years 2000, 2001, and 2002. We also have the option (under section 1833(t)(3)(C)(iii)) of developing a market basket that is specific to hospital outpatient services. We are considering this option, and we solicit comments on possible sources of data that are suitable for constructing a market basket specific to hospital outpatient services.

H. Outlier Payments

Section 1833(t)(2)(E) of the Act requires us to establish in a budget-neutral manner other adjustments that we determine are necessary to ensure equitable payments, such as outlier adjustments or adjustments for certain classes of hospitals. We considered several factors to evaluate the necessity of an outlier adjustment policy.

The most relevant factor is that the proposed system has minimal packaging. Unlike the DRG system for inpatient services, where a patient can be classified into only one payment group during an inpatient stay, payment can be made for a number of APC groups for a given patient on a given day. If multiple services are delivered, payments will be made for multiple APCs. Because a hospital will receive payment for each service furnished, we believe this greatly reduces the need for an outlier adjustment.

Another relevant factor is that critical care services have been isolated into their own APC. Payment for the critical care APC is based on median hospital costs of critical care services. Therefore, payments for this group will reflect the intensity and associated higher costs of this type of medical care.

Even if critical care is not delivered, higher payment will be made for more serious cases. Payments for medical visits to the emergency room will be made at three incremental levels of intensity, and additional payments will be made for any other laboratory work, x-rays, or surgical interventions resulting from the visit.

Upon consideration of the above factors, we do not believe that an outlier adjustment is necessary to ensure equitable payments.

I. Adjustments for Specific Classes of Hospitals

As part of the analysis to determine whether payment adjustments would be proposed for the outpatient prospective payment system, we conducted extensive regression analysis of the relationship between outpatient hospital costs (calculated as hospital outpatient operating and capital cost per unit) and several factors that affect costs. The latter included variables used in estimating similar models for the inpatient PPS, as well as several variables unique to hospital outpatient departments. We considered all costs and services for each hospital relevant to the proposed payment system. Ultimately, we decided not to propose any adjustments to the Federal payment other than the wage index used to adjust for local variation in labor costs at this time. While this reflects a difference in policy relative to inpatient PPS, the proposed outpatient PPS is fundamentally different. Specifically, the outpatient system has limited packaging, so variations in costs are limited to the resources used to produce a single procedure. Cost variations in the inpatient system, however, also can be attributed to variation in the intensity of services bundled under a single rate. Therefore, variations in outpatient cost per unit among hospitals are expected to be small relative to the variations in inpatient cost per discharge that have been estimated in the past.

We began our analysis by examining the distribution of service mix and cost per unit (or cost per service) among various types of hospitals. This analysis revealed some extreme values of cost per unit among types of hospitals, especially major teaching hospitals,

hospitals with trauma centers, and eye and ear hospitals. These costs were 200 percent to 400 percent higher than the average cost per unit for all hospitals. Because costs are measured on a per unit basis, values of this magnitude suggested problems both with identifying procedure codes and properly entering the correct unit of measurement (times performed, minutes of treatment, etc.). Under the current payment system, hospitals will be fully reimbursed for their services even if claims do not contain all the procedure codes that would be associated with revenue centers billed. A consistent practice of such under-coding would lead to very high costs associated with a single unit.

The presence of these extreme values also suggested that a few hospitals could unduly influence the distribution of hospital outpatient cost per unit in our regression analysis. Individual bills were not edited for extreme unit costs. However, even removing cost outliers at the bill-level might not have eliminated these extreme variations at the hospital level. A single under-coded bill might not meet outlier thresholds, but the combined effects of coding differences on all of a hospital's bills could create much higher or lower unit costs.

In light of the lack of trimming for outlier/error costs at the bill level, the possibility of outlier hospitals skewing the distribution of cost per unit, and the hospital-level analysis for payment adjustments argued for an edit on cost per unit at the hospital level. The distribution of cost per unit more closely resembles a lognormal distribution than a normal distribution; there are no negative costs and the average cost is greater than the median cost. We identified outliers using the mean and standard deviation of the natural logarithm of cost per unit. Taking the natural logarithm of any variable compresses the distribution and minimizes the impact of the most unusual bills in the determination of the mean. The compressed distribution also makes it more difficult to identify outliers.

We removed 83 hospitals through an edit of three standard deviations from the mean of the logged unit costs: 51 hospitals with a logged cost per unit exceeding three standard deviations above the mean and 32 hospitals with a logged cost per unit less than three standard deviations below the mean. Removing outlier hospitals greatly improved the distribution of unit costs among types of hospitals. The exempted Maryland hospitals were also excluded from the analysis. However, we included the 10 cancer hospitals. After we removed the 54 exempted Maryland hospitals, outlier hospitals, and hospitals for which we could not identify payment variables, we were left with 5,419 hospitals for analysis. Our regression analyses use this set of hospitals.

A variety of regression models have become the standard of practice for examining hospital cost variation and analyzing potential payment adjustments. We looked at two standard models: fully specified explanatory models to examine the impact of all relevant factors that might potentially affect outpatient hospital cost per unit and payment models that examine the impacts of those factors used to determine payment rates. The payment models standardize the dependent variable, hospital outpatient cost per unit, by service mix to capture the relationship between the APC weights and payment under the PPS, rather than a statistical relationship between service mix and costs. Both unweighted regressions and regressions weighted by volume were examined. All regressions employed a double log or semi-log specification. References to logs throughout this discussion refer to the natural logarithm, and the geometric mean is the mean of the natural logarithm of values. Our dependent variable was total hospital outpatient cost per unit.

We used payment variables from the inpatient prospective payment system, including disproportionate share patient percentage, both capital and operating teaching variables (resident to average daily census and resident to bed ratios respectively), and dummy variables to account for location in a rural, large urban, and other urban area. We also looked at a modified teaching variable that reflects outpatient volume, several dummy variables unique to outpatient departments, such as the presence of a trauma unit, and the difference in costs among various types of TEFRA hospitals and cancer hospitals. A discussion of the major payment variables and our findings appears below.

Service Mix Index

Using APC weights and the number of services provided in each APC, we calculated an average APC weight, or service mix, for each hospital. We also calculated a ''discounted'' service mix that considers the reduced weight for additional surgical procedures performed at the same time, which is consistent with the proposed payment system. The national average service mix is 1.43, and the national average service mix discounted for multiple procedures is 1.45. The differences between the two are negligible due to the low volume of services subject to discounting, and they proved almost interchangeable in the adjustment regressions. We did use the discounted service mix for our regressions because it reflects the proposed policy.

Since APC weights are calculated from costs, we would expect approximately a one to one, or proportional, relationship between service mix and hospital outpatient cost per unit. That is, we expect the coefficient of the service mix to be one in a regression of outpatient cost per unit on the service mix. However, initial payment regressions of hospital outpatient cost per unit on service mix and the wage index revealed a coefficient of 0.68, suggesting that the calculated service mix increases faster than cost per unit; a 10 percent increase in the service mix is associated with a 6.8 percent increase in costs.

This estimated relationship prompted a preliminary analysis of the relationship between geometric means and median cost per unit within each APC. If per unit cost within APCs is distributed log normally, the median and the geometric mean are equivalent. However, if the distribution of costs within APCs is skewed, then the median may differ from the geometric mean. Because the dependent variable in the regression models is the natural log of hospital outpatient cost per unit, a systematic difference between the geometric mean of cost per unit and median cost per unit could explain the lack of one to one relationship between hospital service mix and hospital cost per service. Weighting the regression equation by the volume of services, essentially giving greater weight to the relationship between service mix and unit costs for hospitals with a higher volume of services, increases the relationship to 7.5 percent. Higher volume hospitals tend to have a higher service mix and higher service costs.

A limited analysis of unit costs for selected APCs demonstrated that, in general, in APCs with low relative weights, median hospital cost per unit is lower than the geometric mean of logged hospital cost per unit, and, in APCs with high relative weights, median hospital cost per unit is generally higher than the geometric mean. This would lead to a greater spread in a hospital's service mix than appears in their actual cost per unit, and would provide an explanation for the less than proportional relationship that was estimated to exist between service mix and cost per unit. A regression of cost per unit on a service mix derived from weights based on the geometric

mean and the wage index demonstrated better correlation; a 10 percent increase in service mix led to a 7.7 percent increase in cost per unit. Weighting this regression equation by the volume of services increases the relationship to 9.1 percent, suggesting that the higher service mix of higher volume hospitals better tracks those hospitals' cost per unit.

Labor Share

The coefficient of the hospital wage index is the estimated percentage change in costs attributable to a 1 percent increase in the wage index. This coefficient provides an estimate of the share of outpatient hospital unit costs that are attributable to labor. Depending on the model specification, the coefficient ranged from 0.51 to 0.68 reflecting a labor share between 50 and 70 percent. The coefficient from a fully specified payment regression of the hospital cost per unit standardized for the service mix on the wage index, disproportionate share patient percentage, modified teaching, rural, and urban variables is approximately 0.60, suggesting a labor share of 60 percent. Even though we ultimately decided that we would not propose additional adjustments, we believe that the coefficient from this specification provides the best estimate of the labor share for the proposed system. This judgment was based on a policy to use a labor share that reflected the relationship between the wage index and costs, rather than the effects of correlated factors. The explanatory regression model that has a dependent variable of unstandardized hospital outpatient cost per unit also implies a labor share of 60 percent across most specifications.

Teaching Intensity and Disproportionate Share Patient Percentage

For the inpatient PPS, the intensity of teaching programs has typically been measured by the resident to bed ratio or resident to average daily census ratio. Early in our regression analysis, we used resident to the average daily census of inpatient days, the teaching variable from inpatient capital PPS. The results suggested that costs increase somewhat with the size of the teaching program ($p<0.05$). However, we believed that this ratio could not adequately represent teaching hospitals with large outpatient departments relative to the size of their inpatient operations. We modified the resident to average daily census variable to reflect the ratio of residents to combined inpatient and outpatient utilization. To accomplish this, we calculated the ratio of inpatient costs per day to outpatient costs per unit for each hospital, and we used this ratio to convert hospital services into inpatient day equivalents. We combined both inpatient days and outpatient day equivalents to get a ratio of residents to inpatient and outpatient days. Since we cannot, at this time, allocate residents to inpatient and outpatient settings, we could not estimate a teaching variable based on residents to outpatient volume alone.

We created the disproportionate share patient percentage variable by adding the percentage of inpatient days attributable to Medicaid patients to the percentage of Medicare patients receiving Supplemental Security Income. In most regression specifications, the disproportionate share percentage was positive, small in magnitude, and significant ($p<0.05$). These coefficients imply that a hospital with a 40 percent disproportionate share percentage would be approximately 4.5 percent [calculated $(e^{(DSHP*0.11}-1)*100$] more costly than hospitals without any low-income patients. Teaching intensity variables were not significant in un-weighted regressions ($p>0.05$). However, they were positive and significant in regressions weighted by number of services. The teaching coefficient implies that a hospital with a resident to combined inpatient and outpatient ''days'' ratio of 0.35 would be 2.4 percent [calculated $((1+IME)^{0.08}-1)*100$] more costly than hospitals with no residents.

We also estimated several regression specifications to determine if there were thresholds for the estimated impacts of teaching and disproportionate share patient percentage on costs. We determined that positive and significant estimated differences do not occur for hospitals whose disproportionate share percentage is less than 0.40. Significant effects for the teaching variable do not occur for hospitals whose ratio of residents to inpatient and outpatient days is less than 0.32. We used these results to estimate a new disproportionate share patient percentage based on a 0.30 threshold and a ratio of residents to inpatient and outpatient ''days'' based on a 0.28 threshold. We chose these thresholds by identifying the point at which the relationship between the unit costs and the teaching intensity or disproportionate share patient percentage becomes positive rather than significant because of the lack of significance associated with the teaching variable and because the small coefficient for the disproportionate share variable led to intermittent significance for higher values. We subtracted these thresholds from the original variable to create new teaching and disproportionate share patient percentage variables. Subtracting the threshold removes the effect of values that are not significantly related to cost per unit and eliminates the sudden increase (notch effect) in the disproportionate share patient percentage and teaching variable at the threshold level. The new variables suggest that a hospital with a disproportionate share patient percentage 10 points higher than the 30 percent threshold is approximately 2.3 percent more costly [calculated $(e^{DSHP*0.23}-1)*100$] and that a hospital with a ratio of residents to inpatient and outpatient utilization 0.07 higher than the 0.28 threshold is approximately 0.75 percent more costly [calculated $((1+IME)^{0.11}-1)*100$].

Urban and Rural Location

We also estimated difference in hospital outpatient costs between rural, large urban, and other urban areas. In almost all of the regression models, both explanatory and payment, the rural dummy variable was positive and significant ($p<0.05$). Rural hospitals had approximately 8 percent higher standardized unit costs than urban hospitals. In all of the regression models, large urban hospitals were not significantly different from other urban hospitals.

TEFRA and Cancer Hospitals

We also found that some types of TEFRA hospitals (long-term care, children's, and psychiatric) and the ten cancer hospitals have significantly ($p<0.05$) higher unit costs standardized for service mix. Cancer, children's, and long term care hospitals demonstrated standardized unit costs that were at least 20 percent higher than other hospitals. We believe that these significantly higher costs largely can be attributed to under-coding because proper coding is not required for the payment of many services under the current system, especially medical visits. Poor coding would affect calculations of both service mix and cost per unit.

Estimated Payments

The appropriateness of potential payment adjustments must be based on both cost effects estimated by regression analysis and other factors including simulated payment impacts. We simulated the impact of the proposed system on hospitals by calculating the percentage difference between payments made under current law and payments

under the proposed system (column 3). Section X. contains a more complete table that considers the impact of proposed payments on additional classes of hospitals, including TEFRA and cancer hospitals. Although Column 3 represents the net effect of the new PPS on hospitals, we thought it was necessary to show the impacts on hospitals of simply changing the payment system without including the effects of the overall reduced payment to hospitals because the PPS system is not budget neutral to current payment. To reiterate, the conversion factor is set by summing Medicare payments under the current system and beneficiary copayment under the new system and dividing by the sum of the relative weights. Beneficiary copayments under the new system will reduce overall payments to most hospitals because 20 percent of the median group charges is less than 20 percent of actual charges. Therefore, we simulated the impacts as though the conversion factor were set as if the system were to be budget neutral. Column 4 demonstrates the distributional impacts resulting from implementing the new system after eliminating the overall reduction in payment most hospitals will experience due to the effect of the methodology used to set the conversion factor. We believe the column 4 percentage differences are what we should examine since any adjustment we would consider should correct for inequities caused by moving to a PPS (not the legislated reduction in total payment). Therefore, we based our decision about adjustments on these percentage differences rather than percentages combining the PPS and the overall reduction in coinsurance amounts required by law. We also estimated payment to cost ratios associated with the new payment methods and the percent change in total Medicare payments. All simulations used a labor share of 60 percent. The table below shows the results of two simulations. The first contains only the wage index adjustment to the APC rates. The second also includes the threshold adjustments for disproportionate share patient percentage and teaching intensity discussed above.

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CHANGES FOR 1999
OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

			No Teaching and DSH Adjustments				Teaching and DSH Adjustments			
	Number of hospitals (1)	Outpatient percent (2)	Percent change in Medicare Outpatient payment (3)	Conversion Factor Effect removed (4)	Stand-ardized payment to cost ratio (5)	Percent change in total Medicare payments (6)	Percent change in Medicare Outpatient payment (7)	Conversion Factor Effect removed (8)	Standardized payment to cost ratio (9)	Percent change in total Medicare payments (10)
ALL HOSPITALS	5,419	9.9	-3.8	-0.0	1.0000	-0.4	-3.8	-0.0	1.0000	-0.4
NON-TEFRA HOSPITALS	4,864	10.0	-3.7	0.1	1.0011	-0.4	-3.7	0.1	1.0012	-0.4
GEOGRAPHIC LOCATION: URBAN HOSPITALS	2,677	9.3	-3.3	0.5	1.0057	-0.3	-3.2	0.6	1.0069	-0.3
LARGE URBAN AREAS	1,516	9.1	-5.0	-1.3	0.9868	-0.5	-4.6	-0.8	0.9915	-0.4
OTHER URBAN AREAS	1,161	9.6	-0.9	3.0	1.0332	-0.1	-1.3	2.6	1.0293	-0.1
RURAL HOSPITALS	2,187	14.7	-5.2	-1.5	0.9816	-0.8	-5.7	-1.9	0.9770	-0.8
VOLUME (URBAN)										
0- 4,999 UNITS	278	12.1	-15.6	-12.3	0.8164	-1.9	-14.8	-11.4	0.8244	-1.8
5,000- 10,999 UNITS	442	9.8	-6.3	-2.6	0.9559	-0.6	-5.8	-2.1	0.9607	-0.6
11,000- 20,999 UNITS	599	9.1	-5.8	-2.1	0.9574	-0.5	-5.6	-1.9	0.9593	-0.5
21,000- 42,999 UNITS	780	8.7	-3.6	0.2	1.0071	-0.3	-3.9	-0.1	1.0040	-0.3
43,000 OR MORE UNITS	578	9.7	-2.0	1.9	1.0266	-0.2	-1.7	2.2	1.0299	-0.2
VOLUME (RURAL)										
0- 4,999 UNITS	816	18.2	-17.0	-13.7	0.7799	-3.1	-17.2	-13.9	0.7781	-3.1
5,000 - 10,999 UNITS	694	15.8	-10.0	-6.5	0.9144	-1.6	-10.3	-6.7	0.9122	-1.6
11,000 - 20,999 UNITS	420	14.6	-5.8	-2.1	0.9848	-0.8	-6.2	-2.5	0.9812	-0.9
21,000- 42,999 UNITS	215	13.5	-1.8	2.0	1.0368	-0.2	-2.5	1.3	1.0294	-0.3
43,000 OR MORE UNITS	42	13.2	5.3	9.4	1.1263	0.7	4.6	8.7	1.1190	0.6

	Number of hospitals (1)	Outpatient percent (2)	No Teaching and DSH Adjustments: Percent change in Medicare Outpatient payment (3)	No Teaching and DSH Adjustments: Conversion Factor Effect removed (4)	No Teaching and DSH Adjustments: Stand-ardized payment to cost ratio (5)	No Teaching and DSH Adjustments: Percent change in total Medicare payments (6)	Teaching and DSH Adjustments: Percent change in Medicare Outpatient payment (7)	Teaching and DSH Adjustments: Conversion Factor Effect removed (8)	Teaching and DSH Adjustments: Standardized payment to cost ratio (9)	Teaching and DSH Adjustments: Percent change in total Medicare payments (10)
TEACHING STATUS										
NON-TEACHING	3,847	11.2	-3.1	0.7	1.0031	-0.3	-3.7	0.1	0.9973	-0.4
FEWER THAN 100 RESIDENTS	766	9.1	-1.8	2.0	1.0326	-0.2	-2.4	1.5	1.0266	-0.2
100 OR MORE RESIDENTS	250	9.2	-9.4	-5.8	0.9331	-0.9	-6.4	-2.7	0.9643	-0.6
DISPROPORTIONATE SHARE PATIENT RATIO										
0	25	25.1	-0.3	3.6	0.9250	-0.1	-1.2	2.7	0.9175	-0.3
0.001- 0.099	916	10.3	-4.9	-1.1	0.9780	-0.5	-5.8	-2.1	0.9682	-0.6
0.100- 0.159	1,016	10.9	-0.9	3.0	1.0447	-0.1	-1.9	1.9	1.0337	-0.2
0.160- 0.299	1,613	10.1	-3.0	0.8	1.0113	-0.3	-3.7	0.0	1.0039	-0.4
GREATER THAN 0.299	1,294	9.2	-6.6	-2.9	0.9617	-0.6	-3.5	0.3	0.9934	-0.3

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Based on our analyses, we are not proposing to make adjustments to the outpatient payment rates for disproportionate share patient percentage and teaching intensity and rural location for the following reasons.

1. Estimated effects of teaching intensity and disproportionate share patient percentage on costs were small and, in some cases, not statistically significant.

2. Payment impacts without such adjustments do not vary considerably, the largest being a reduction of 5.8 percent for major teaching hospitals. These impacts should also be evaluated in terms of the overall effect on Medicare payments since on average, outpatient services account for 10 percent of hospitals' Medicare payments. For example, the associated reduction of total Medicare payments for major teaching hospitals would be about 1 percent.

3. With the threshold adjustments we considered, estimated payment reductions for rural hospitals would be 1.9 percent under the proposed system, rather than 1.5 percent. These hospitals also receive a greater percent of their Medicare income (14.7 percent) from providing outpatient services. Similarly, payment reductions for low-volume rural hospitals would be 13.9 percent of current payments, rather than 13.7 percent, and these hospitals also earn a greater percentage of their Medicare income (18.2 percent) from providing outpatient services. Because of these potential shifts in payments, any adjustment should be based on stronger analytic results than those found with the current data.

4. We also believe the issue of payment adjustments should be reexamined using data from initial years of the implemented system because current cost calculations and relationships among key factors and costs probably are affected by variation in coding patterns.

5. HCFA is working towards standardizing payment across all sites of service. Fewer adjustments to the outpatient PPS would allow HCFA to move ahead more quickly with this approach.

6. We believe that we should further analyze the impact of basing APC weight calculations on the median rather than the geometric mean because better correlation between costs and service mix would impact the size of adjustments.

Although the payment simulations show potentially large percentage losses and low payment to cost ratios for low-volume hospitals, we are not proposing an adjustment for volume. The low-volume hospitals get a much greater percent of their Medicare income from the provision of outpatient services than the average, and total Medicare payments would drop by 3.1 percent for rural low-volume hospitals and 1.8 percent for urban low-volume hospitals. Low-volume hospitals have higher than average standardized unit costs, which may be attributable to economies of scale, under-coding, or cost allocations to the outpatient departments that are not volume related. However, an adjustment to the rates based on volume alone might reward inefficiency and create adverse incentives such as a reduction in services in order to increase payment rates. Moreover, these hospitals do not comprise a large enough proportion of other hospital types to substantially benefit from other adjustments (for example, teaching or disproportionate share).

We are particularly concerned about the potential impact of the outpatient PPS on low-volume rural hospitals that are sole community hospitals or Medicare-dependent hospitals. Approximately 60 percent of the rural hospitals furnishing fewer than 5,000 visits fall into these categories. We are investigating the reasons for their higher costs and are assessing whether a temporary adjustment is needed to moderate the impact of moving to an outpatient PPS. One option we are considering would be to phase-in the outpatient PPS for low-volume Medicare-dependent and sole community hospitals by paying a portion of the payment based on PPS rates and a portion based on the current payment system. For example, payment could be based on 75 percent of payments under the current system and 25 percent on PPS rates in the first year, 50 percent current system payments and 50 percent PPS rates in the second year, 25 percent current system payments and 75 percent PPS rates in the third year, and completely on PPS rates in subsequent years. Another option we are considering would phase-in outpatient PPS if a low-volume sole community hospital or Medicare-dependent hospital has a negative Medicare margin for outpatient services. For example, payment could be based on the amount payable under outpatient PPS plus a percentage of the difference between those amounts and the amounts payable under the current system. The percentage of the difference that would be payable could phase down, for example, 75 percent in year one of implementation, 50 percent in year 2, 25 percent in year 3, and no adjustment in year 4 and subsequent years. We solicit comment on this and other alternatives we might consider. By statute, any adjustment would have to be budget neutral.

We also are not proposing adjustments for cancer or TEFRA hospitals at this time. We believe that claims from cancer and TEFRA hospitals have been under-coded for many of the services cancer hospitals provide due to the lack of payment incentives for proper coding of these services under the current system. Further analysis will be conducted to determine if current coding practices explain the negative impact. If we determine that cancer hospitals would be unduly harmed because of the new outpatient PPS, we will consider whether an adjustment or perhaps a transition period is needed to moderate the impact. By statute, any adjustment would have to be budget neutral.

We do not believe that this action will restrict beneficiary access because other hospitals provide many of the same services provided at TEFRA hospitals. In addition, children's and free-standing psychiatric hospitals are less dependent than other hospitals on Medicare revenues. Finally, the remaining classes of TEFRA hospitals, rehabilitation and long-term care, lose a much smaller percentage of their total Medicare income, 3.7 and 3.5 percent respectively than the average for all facilities.

We are not proposing adjustments for any eye and ear or trauma hospitals because payment simulations demonstrated an increase in payments under the proposed PPS. We will assess the need for additional adjustments and make any appropriate changes as data become available under the new system.

J. Volume Control Measures

Section 1833(t)(2)(F) of the Act requires us to develop a method for controlling unnecessary increases in the volume of covered outpatient department services, including partial hospitalization services in CMHCs. If the volume of services paid for increases beyond amounts established through methodologies determined in section 1833(t)(2)(F), section 1833(t)(6)(C) provides that the update to the conversion factor may be adjusted. MedPAC recommends in its report to the Congress that we implement an expenditure cap to help control spending for hospital outpatient services and that we monitor hospital outpatient volume to ensure that access to services and quality of care are not reduced under a cap.

In this proposed rule, we are proposing a volume control measure for services furnished in CY 2000. In the

proposed rule for rates that would be effective in CY 2001, we plan to propose an appropriate method for determining expenditure targets for services furnished in CY 2001 and subsequent years, following completion of further analysis of how that target should be computed. Later in this section, we discuss several possible approaches for controlling the volume of hospital outpatient services furnished in CY 2001 and subsequent years.

Pursuant to section 1833(t)(2)(F) and consistent with section 1833(t)(6)(C), we are proposing to update the target amount specified under section 1833(t)(3)(A) for CY 1999 as an expenditure target for services furnished in CY 2000. We will update the CY 1999 target for inflation (based on the projected change in the hospital market basket minus one percentage point) and estimated changes in the volume and intensity of hospital outpatient services and estimated Part B fee-for-service changes in enrollment. If volume exceeds the target for CY 2000, we are proposing to adjust the update to the conversion factor for CY 2002. We will compare the CY 2000 target to an estimate of CY 2000 actual payments to hospitals. (HCFA's Office of the Actuary will determine the CY 2000 actual payments using the best available data.) If unnecessary volume increases, as reflected by expenditure levels, cause payments to exceed the target, we will determine the percentage by which the target is exceeded, and adjust the CY 2002 update to the conversion factor by the same percentage.

In conjunction with the Office of Inspector General, we are proposing to do further work to assure that only payments made in accordance with existing Medicare law and regulations were used in the calculation of the target amount. If this work reveals that adjustments to the target amount and expenditure ceiling are warranted, we will address this issue in a future rule.

When the inpatient PPS was implemented, the packaging of all services provided during an admission under a single rate was the primary method of volume control. This method was appropriate because the concern was the intensity of services per admission, rather than the number of admissions, which was generally stable. For outpatient department services, there has been rapid growth in the intensity of ancillary services per procedure. We believe that greater packaging of these services might provide volume control. However, because the hospital outpatient PPS will not initially include a significant degree of packaging, we are examining a number of mechanisms to control unnecessary increases, as reflected by expenditure levels, in the volume of covered outpatient department services. The volume of services is a significant concern, particularly during the first few years of the outpatient PPS, because of the possible incentives under PPS to increase utilization.

Although the updated target amount provides a basis against which we can measure year 2000 actual payments, we need to develop an approach for establishing a volume control measure for years 2001 and beyond. Because of the complexities involved in developing such a system, we do not plan to propose a method for future years (2001 and beyond) until we issue our notice of proposed rulemaking for CY 2001, but we want to open a discussion now, so that we can obtain comments that we can use in developing a proposal.

One possible mechanism to control unnecessary increases in the volume of outpatient services paid for under the outpatient PPS is to expand the sustainable growth rate (SGR) system for physician services, which is required under section 1848(d)(3) of the Act, as amended by section 4502 of the BBA, to take into account hospital outpatient services. Physicians typically are responsible for ordering medical services and are thus responsible for determining a substantial portion of hospital outpatient volume. Expanding the SGR system for physician services to include hospital outpatient services would provide added incentives for physicians to evaluate the necessity of orders for hospital outpatient services.

A second possible mechanism would be to expand the SGR system for physician services to include all ambulatory services, for example, services in hospital outpatient departments and ASCs, and to use this expanded SGR system to establish updates for the ambulatory facility payments as well as for physician fee schedule updates. This method would spread volume control incentives more evenly across the ambulatory sector. It would more closely align physician and facility incentives and be less sensitive than a hospital-outpatient-department-only SGR to shifts in site of service.

A third approach to controlling unnecessary growth in the volume of hospital outpatient services is to modify the physician SGR method and incorporate it into the hospital outpatient department payment system. That is, as in the physician payment context, an SGR value for hospital outpatient services would be calculated and payment updates for these services would be reduced if volume increases result in expenditures above target levels.

We believe the third option of linking updates of the outpatient department conversion factor to an SGR system is the most feasible approach to take initially. Additional study, analysis, and possible legislative modification would be necessary before we could consider implementing either of the first two options discussed above. We acknowledge that, to the extent that hospital outpatient volume is physician driven, an outpatient SGR could arguably be viewed as unnecessarily and unfairly penalizing facilities. Moreover, because sites of ambulatory care are relatively interchangeable with respect to the delivery of outpatient services, setting appropriate targets for hospital outpatient departments alone could be difficult. However, an outpatient SGR system would parallel the SGR system created for physician services under section 4502 of the BBA. Physician volume issues have been extensively analyzed by MedPAC, and the SGR system for physicians has evolved as a feasible method for volume control. Many outpatient PPS issues are similar to physician issues because changes in technology and places of service can affect expenditures for both hospital outpatient departments and physicians.

The outpatient SGR system would base volume and intensity growth allowances for services under the outpatient PPS on the growth in the general economy. Other factors in determining the target rate of growth include medical inflation, changes in enrollment, and changes in spending due to changes in the law or regulations. The outpatient SGR would be calculated as the product of—

(1) The annual update to the conversion factor (described in section V.G.3. of this preamble), which is the outpatient market basket percentage increase reduced by one percentage point for the years 2000, 2001, and 2002.

(2) The percentage increase or decrease in Part B enrollees (excluding those enrolled in Medicare+Choice) from one year to the next;

(3) The projected growth in the real gross domestic product per capita (or real gross domestic product per capita plus an appropriate factor for recent outpatient department services growth) from the previous year to the year involved; and

(4) The percentage change in spending for outpatient department services resulting from changes in law and regulations from one year to the next.

This growth rate system would be used in setting annual updates to the conversion factor for hospital outpatient services. Pursuant to section 1833(t)(2)(F) of the Act, and consistent with section 1833(t)(6)(C), we would lower the annual update to the conversion factor for a given year if volume increases cause expenditures to exceed the target amount in a previous year. While we think using an outpatient department SGR is the most feasible option in the short term, in the long term we would like to develop a more integrated approach that addresses physicians and ASCs, as well as outpatient departments. In addition to requesting comments on our proposed volume control measure for services furnished in CY 2000, we specifically solicit comments on the appropriateness of applying the SGR method directly to payments made under the outpatient PPS for future years. We also welcome comments on the development of a long-term integrated system that we would consider as we develop possible future proposals. In our final rule, we will respond to comments on our proposed volume control measure for services furnished in CY 2000. We do not intend to respond to comments concerning the development of an SGR system for services furnished after CY 2000, an integrated system, or any other approach. However, we will use any comments we receive in developing a proposal we will make next year for volume control measures to be applied to services furnished after CY 2000.

K. Prohibition Against Administrative or Judicial Review

Section 1833(t)(9) of the Act prohibits administrative or judicial review of the PPS classification system, the groups, relative payment weights, adjustment factors, other adjustments, volume control methods, calculation of base amounts, periodic control methods, periodic adjustments, and the establishment of a separate conversion factor for cancer hospitals.

VI. Hospital Outpatient Clinics and Other Provider-Based Entities

A. Background

The Medicare law (section 1861(u) of the Act) lists the types of facilities that are regarded as providers of services, but does not use or define the term ''provider-based.'' However, from the beginning of the Medicare program, some providers, which are referred to in this section as ''main providers,'' have owned and operated other facilities, such as SNFs or HHAs, that were administered financially and clinically by the main provider. The subordinate facilities may have been located on the main provider campus or may have been located away from the main provider. In order to accommodate the financial integration of the two facilities without creating an administrative burden, we have permitted the subordinate facility to be considered provider-based. The determination of provider-based status allowed the main provider to achieve certain economies of scale. To the extent that overhead costs of the main provider, such as administrative, general, housekeeping, etc. were shared by the subsidiary facility, these costs were allowed to flow to the subordinate facility through the cost allocation process in the cost report. This was considered appropriate because these facilities were also operationally integrated, and the provider-based facility was sharing the overhead costs and revenue producing services controlled by the main provider.

Before implementation of the hospital inpatient PPS in 1983, there was little incentive for providers to affiliate with one another merely to increase Medicare revenues or to misrepresent themselves as being provider-based, since at that time each provider was paid primarily on a retrospective, cost-based system. At that time, it was in the best interest of both the Medicare program and the providers to allow the subordinate facilities to claim provider-based status, because the main providers achieved certain economies, primarily on overhead costs, due to the low incremental nature of the additional costs incurred. For example, the billing department of a main provider could usually accommodate the additional workload associated with a provider-based facility by hiring an additional billing clerk, instead of incurring the cost of a separate billing department for the provider-based facility. This economy of scale would usually extend to the other overhead costs incurred by the main provider, because the free-standing facility was generally more costly to maintain than one that was provider-based. This was due primarily to the savings on overhead costs that were accomplished by the merging of the free-standing facility into the main provider and having it integrated with the main provider. Although there were several limited guidelines outlining the conditions for certain provider-based situations, we devoted few resources to reviewing provider compliance, because there was little incentive for providers to use this designation inappropriately.

Since 1983, the number of provider-based facilities has increased significantly. For example, in July of 1982, there were 481 provider-based HHAs as compared with 2,577 provider-based HHAs in October of 1996. This was an increase of 435.75 percent in the 13 years since the PPS was established. In addition, many hospitals now have a large number of outpatient clinics, often located at various sites.

We believe the growth in the number of facilities and organizations claiming to be provider-based has occurred for several reasons. First, the PPS established payment rates using base year costs that included provider overhead. Health care providers, looking for ways to increase their Medicare revenues, realized that if they established provider-based facilities or organizations that were still subject to the reasonable cost principles, they would then be able to shift some of the overhead from the hospital inpatient operating costs to these provider-based facilities or organizations. The PPS main provider would be paid a PPS payment that was intended to cover overhead costs, as well as being reimbursed on a reasonable cost basis based on Medicare's share of the overhead costs for the services furnished by the provider-based facility or organization. A main provider that is excluded from PPS and subject to the rate-of-increase limits would also benefit from shifting its overhead to the subordinate provider-based facility or organization. This cost shifting would enable it to increase its payment by being paid for the Medicare share of the diverted overhead on a cost-based methodology, as well as bringing its costs below the rate-of-increase limit. The main provider could then share in the incentive payment by having its costs come in below the target rate.

More recently, other factors have combined to create incentives for providers to affiliate with one another and to acquire control of nonprovider treatment settings, such as physician offices. Integrated delivery systems offer a wide variety of health care services and can assume responsibility for entire episodes of a patient's illness. These systems are attractive to patients, who seek continuity of care, and to businesses seeking a single source of health services for their employees. The resulting growth in the number of patients enrolled by these integrated delivery systems has created a powerful incentive for affiliations. In addition, hospitals rely on referrals from physicians to assure a steady stream of patients, and they have begun to purchase physician practices and integrate them into their outpatient operations. This trend also has created

incentives for hospitals to affiliate with physician practices.

B. Effects on Medicare

For several reasons, it is essential that we ensure that decisions regarding provider-based status are made appropriately, and that facilities or organizations are not recognized as provider-based unless they are in fact integral and subordinate parts of the main provider. As noted earlier, in cases where main providers are paid under the PPS and subordinate facilities or organizations are paid under the reasonable cost reimbursement method (section 1861(v)(1)(A) of the Act and 42 CFR part 413), a provider-based determination could allow the main provider to shift overhead costs to cost centers that are paid on a cost basis and thereby increase Medicare payments with no commensurate benefit to the Medicare program or its beneficiaries.

Payments for services furnished in a hospital outpatient clinic generally include both a facility payment and payment for the professional services of a physician. The combined payments are typically higher than the payment for comparable services furnished in a physician office, where a separate facility fee is not payable. In many cases, there is also an increase in beneficiaries' out-of-pocket expenses compared to services furnished in a physician office. For example, when a beneficiary is treated in a physician office, the only payment made is Part B payment to the physician for his or her professional services, under the physician fee schedule. The single payment made under the physician fee schedule pays for the physician's work and includes a component for practice expense. The beneficiary's coinsurance is based on 20 percent of the physician fee schedule amount. However, if the same service is furnished in a hospital outpatient clinic, Medicare Part B payment for a facility fee is also made to the hospital, in addition to the physician's payment (which may include a smaller practice expense component). Thus, for the same visit, the beneficiary is also subject to the Part B coinsurance for the hospital's facility fee. Beneficiaries are responsible for coinsurance based on 20 percent of the hospital's charges (or, the applicable coinsurance amounts under the hospital outpatient PPS).

Provider-based status also raises issues of Medicare coverage. Generally, the services of nonphysician staff furnished in a physician office are covered only as services ''incident to'' the professional services of a physician under section 1861(s)(2)(A) of the Act. This means that a physician must be available on the premises when the service is furnished, in order to provide direct supervision of that service. In hospital outpatient departments, however, we presume that the ''incident to'' requirements are met with respect to hospital services incident to physician services to outpatients (section 1861(s)(2)(B)). The policy assumed the outpatient department was co-located on the hospital premises and staff physicians would be available nearby to provide necessary oversight. It is possible that a hospital outpatient clinic may not be in the immediate vicinity of the hospital and may furnish nonphysician services without actually providing for direct physician supervision of those services. We do not believe that such services should be presumed to meet applicable ''incident to'' requirements. As explained below, it could also present a health and safety risk at a time when the office is staffed with nonphysician personnel who are furnishing medical care with no physician present and available to attend to any unexpected emergency situation that may arise.

Provider-based status for a facility or organization can have other implications for the health and safety of its patients. Hospital outpatient facilities are subject to the Medicare conditions of participation in 42 CFR part 482, including specific requirements covering such crucial areas as adequacy of physician care (§ 482.22, ''Conditions of participation: Medical staff''), and the safety of the physical environment, including compliance with fire safety requirements (§ 482.41, ''Conditions of participation: Physical environment''). Beneficiaries have the right to expect that any outpatient department of a hospital meets applicable conditions of participation and that the facility is capable of providing care commensurate with the general level of care furnished in a hospital outpatient department that is co-located with the inpatient setting. However, the facility claimed as an outpatient department may not have been surveyed for compliance with the conditions of participation and, in some cases, we may not even have been notified of its existence.

The BBA includes several new provisions that can be implemented appropriately only if clear distinctions are made between free-standing and provider-based facilities. Section 4205(a)(1) of the BBA amended section 1833(f) of the Act to extend the per-visit payment limit for rural health clinics (RHCs), which previously applied only to free-standing RHCs, to most provider-based RHCs as well. (The law provides that the limit does not apply to RHCs located in hospitals with less than 50 beds.)

Section 4541 of the BBA amended section 1833 of the Act to establish a prospective system of payment for outpatient physical therapy services (including outpatient speech-language pathology services) and outpatient occupational therapy services furnished after 1998, and to establish a $1,500 annual limit on the amount of payment for such services to each beneficiary. Under sections 1833(g)(1) and (g)(2) of the Act, however, that limit does not apply to services furnished in hospital outpatient departments. Moreover, as explained later in this section of the preamble, there are differences in payment for ambulatory surgical services, depending on whether the services are furnished in a hospital, by an approved ASC, or in a physician office. Further, higher composite rate payments are made to hospital-based ESRD facilities than to free-standing ESRD facilities. Thus, it is essential that we have clear rules for identifying provider-based facilities.

C. Relationship of the ''Provider-Based'' Proposals to Prospective Payment for Outpatient Hospital Services and Effective Date of ''Provider-Based'' Proposals

Although the proposed regulations set forth in new § 413.65 and in the amendment to § 413.24 relate to providers generally, their implementation is crucial to successful implementation of a PPS for outpatient hospital services. No outpatient PPS can succeed if it does not clearly define the services to which it applies. Experience suggests that under the existing policies defining provider-based status, many ambulatory services may be characterized either as physician office services or as services of hospital outpatient departments or clinics or an ASC, depending on the financial incentives involved. Thus, we are publishing these proposed rules to permit clearer distinctions to be made between various types of services, and to ensure that services paid for under the outpatient PPS are of the same type as those included in the data on which the system is based.

As explained in the previous section of this preamble, it is essential that provider-based decisions be made appropriately in all cases, not just those involving outpatient hospital services paid for under a PPS. Therefore, the effective date of these proposals will not be delayed until after an outpatient PPS is in effect. On the contrary, we plan to

implement proposed §§ 413.24(d)(6)(i) and (ii), 413.65, 489.24(b), and 498.3, as revised based on our consideration of public comments, with respect to services furnished on or after 30 days following publication of a final rule.

D. Basis for Current Provider-Based Policy

Although there is no direct statutory requirement to maintain explicit criteria for determination as to provider-based status, there are statutory references acknowledging the existence of this payment outcome. For example, section 1881(b) of the Act provides for separate payment rates for hospital-based (ESRD) facilities.

There is currently no general definition of ''provider-based facility'' in the CFR. However, various sections of the CFR do contain provisions for recognition of specific types of entities as provider-based.

Section 405.2462(a) authorizes payment for RHCs and Federally qualified health centers (FQHCs) as provider-based, if:

(1) The clinic or center is an integral and subordinate part of a hospital, SNF, or HHA participating in Medicare, (that is, a provider of services); and

(2) The clinic or center is operated with other departments of the provider under common licensure, governance, and professional supervision.

Definitions of hospital-based HHAs and SNFs were published in final notices on cost limits for HHAs and SNFs, in the June 5, 1980 (45 FR 38014) and September 4, 1980 (45 FR 58699) issues of the **Federal Register**, respectively. These criteria were identical to one another and were similar to the RHC and FQHC definition but they provided considerably more detail in their description of common governance.

Further, we have provided additional detail regarding the factors to be considered in making determinations regarding provider-based status in our manuals. The Medicare Regional Office Manual at section 6860 provides a list of criteria that should be considered in making a determination regarding provider-based status for clinics. Also, section 2186 of the State Operations Manual provides direction regarding provider-based designation for HHAs.

Program Memorandum A–96–7, published on August 27, 1996, pulled together the instructions previously manualized for specific entity types into a general instruction for the designation of provider-based status to all facilities or organizations. In developing this Program Memorandum, we took information from the State Operations Manual (sections 2024, 2186, and 2242), the Regional Office Manual (section 1060, 2020 and 6865), and §§ 405.2462 and 413.170 of the CFR.

Under the policy we set forth in Program Memorandum A–96–7, the following applicable requirements must be met before an entity can be designated as provider-based for Medicare payment purposes:

1. The entity is physically located in close proximity of the provider where it is based, and both facilities serve the same patient population (for example, from the same service, or catchment area);

2. The entity is an integral and subordinate part of the provider where it is based, and as such, is operated with other departments of that provider under common licensure (except in situations where the State separately licenses the provider-based entity);

3. The entity is included under the accreditation of the provider where it is based (if the provider is accredited by a national accrediting body) and the accrediting body recognizes the entity as part of the provider;

4. The entity is operated under common ownership and control (that is, common governance) by the provider where it is based, as evidenced by the following:

- The entity is subject to common bylaws and operating decisions of the governing body of the provider where it is based;
- The provider has final responsibility for administrative decisions, final approval for personnel actions, and final approval for medical staff appointments in the provider-based entity; and
- The entity functions as a department of the provider where it is based with significant common resource usage of buildings, equipment, and service personnel on a daily basis.

5. The entity director is under the direct day-to-day supervision of the provider where it is located, as evidenced by the following:

- The entity director or individual responsible for day-to-day operations at the entity maintains a daily reporting relationship and is accountable to the Chief Executive Officer of the provider and reports through that individual to the governing body of the provider where the entity is based; and
- Administrative functions of the entity, for example, records, billing, laundry, housekeeping and purchasing are integrated with those of the provider where the entity is based.

6. Clinical services of the entity and the provider where it is located are integrated as evidenced by the following:

- Professional staff of the provider-based entity have clinical privileges in the provider where it is based;
- The medical director of the entity (if the entity has a medical director) maintains a day-to-day reporting relationship to the chief medical officer or other similar official of the provider where it is based;
- All medical staff committees or the professional committees at the provider where the entity is based are responsible for all medical activities in the provider-based entity;
- Medical records for patients treated in the provider-based entity are integrated into the unified records system of the provider where the entity is based;
- Patients treated at the provider-based entity are considered patients of the provider and have full access to all provider services; and
- Patient services provided in the entity are integrated into corresponding inpatient and/or outpatient services, as appropriate, by the provider where it is based.

7. The entity is held out to the public as part of the provider where it is based (for example, patients know they are entering the provider and will be billed accordingly).

8. The entity and the provider where it is based are financially integrated as evidenced by the following:

- The entity and the provider where it is based have an agreement for the sharing of income and expenses, and
- The entity reports its cost in the cost report of the provider where it is based using the same accounting system and the same cost reporting period as the provider where it is based.

Our policy will continue to follow the principles we articulated in Program Memorandum A–96–7 until 30 days after this rule is published as final in the **Federal Register**. After that date, we will apply the policies set forth in the final regulations.

E. Provisions of This Proposed Rule

This proposed rule would add a new § 413.65, stating the appropriate definitions of, and the general requirements for, the determination of ''provider-based'' status. In paragraph (a), we are proposing to define the following terms for purposes of this section: department of a provider, free-standing facility, main provider, provider-based entity, and provider-based status. The definitions used are as follows.

Department of a provider means a facility or organization or clinic that is

either created by, or acquired by, a main provider for the purpose of furnishing health care services under the name, ownership, and financial and administrative control of the main provider in accordance with the provisions of proposed § 413.65. A department of a provider is not licensed or certified to provide services in its own right, and Medicare conditions of participation do not apply to the department as an independent entity. The term ''department of a provider'' does not include an RHC or FQHC; however, an RHC or FQHC could qualify as a provider-based entity.

Free-standing facility means an entity that furnishes health care services to Medicare beneficiaries, and that is not integrated with any other entity as a main provider, a department of a provider, or a provider-based entity.

Main provider means a provider that either creates or acquires ownership of another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Provider-based entity means a provider, or an RHC or FQHC as defined in § 405.2401(b), that is either created by, or acquired by, a main provider for the purpose of furnishing health care services under the name, ownership, and administrative and financial control of the main provider in accordance with the provisions of proposed § 413.65. A provider-based entity is certified to provide services in its own right.

Provider-based status means the relationship between a main provider and a provider-based entity, or a department of a provider, that is in compliance with the provisions of proposed § 413.65.

We are proposing to state explicitly, in new paragraph (b), that a facility or organization is not entitled to be treated as provider-based simply because it or the provider believe it to be provider-based. We also would state that, if a facility or organization seeking provider-based status is located off the campus of a provider, or inclusion of the costs of the facility or organization on the provider's cost report would increase the total costs on that report by at least 5 percent, HCFA will not treat the facility or organization as provider-based for purposes of billing or cost reporting unless the provider has contacted HCFA and obtained a determination of provider-based status. This means that we would not accept billings from the facility or organization as if it were provider-based, and the provider will not be permitted to include costs of the facility or organization on its cost report, unless the acquisition or creation of the facility or organization has been reported to us and we have determined that it is either a department of a provider or a provider-based entity. Further, a facility not located on the campus of a hospital and used as a site of physician services of the kind ordinarily furnished in physician offices will be presumed to be a free-standing facility unless it is determined by HCFA to have provider-based status. For example, a physician office practice purchased by a main provider would not qualify for provider-based status unless it meets all applicable criteria in proposed § 413.65.

We are proposing to require, in new paragraph (c), that a main provider that acquires a facility or organization for which it wishes to claim provider-based status must report its acquisition of the facility or organization to HCFA and furnish all information needed for a determination as to whether the facility or organization meets the criteria in this section for provider-based status. A main provider that has had one or more facilities or organizations determined to have provider-based status also must report to HCFA any material change in the relationship between it and any department or provider-based entity, such as a change in ownership of the entity or entry into a new or different management contract, that could affect the provider-based status of the department or entity.

In new paragraph (d), we propose the requirements for a determination of ''provider-based status.'' In paragraph (d)(1), we would set forth licensure requirements for facilities or organizations seeking provider-based status. Any facility or organization seeking to be a department of a provider would have to be operated under the same license as the main provider. We note that if a State's licensure laws establish restrictions on the type or location of facilities or organizations that can be licensed as part of a provider, we would defer to those restrictions in determining whether a particular facility is a department of the provider. For example, if the hospital licensure laws of a particular State precluded facilities located more than 5 miles from a hospital from being licensed as part of the hospital, we also would not consider those facilities to be a part of the hospital. Provider-based entities would not have to be operated under the same license as the main provider, since in most cases we expect that they would be separately licensed by the State. To take account of possible State-by-State differences in licensure, however, we would require only that a prospective provider-based entity be licensed in accordance with the law of the State in which it is located.

In addition, if a State health facilities' cost review commission, or other agency that has authority to regulate the rates charged by hospitals or other providers in a State, finds that a particular facility or organization is not part of a provider, we also would determine that the facility or organization does not have provider-based status. We believe it would be inappropriate for a facility or organization to be considered free-standing for State ratesetting purposes, but provider-based status under Medicare.

In paragraph (d)(2), we would require that a facility or organization be under the ownership and control of the main provider. In particular, we would require that the facility or organization be 100 percent owned by the provider, that the main provider and a facility or organization seeking provider-based status have the same governing body, and that the facility or organization be operated under the same organizational documents as the main provider. For example, the facility seeking provider-based status would have to be subject to the bylaws and operating decisions of the governing body of the main provider. In addition, we would require that the main provider have final responsibility for administrative decisions, final approval for outside contracts, final responsibility for personnel policies, and final approval for medical staff appointments in the department or entity.

In paragraph (d)(3), with respect to administration and direct supervision of the main provider, we are proposing to require that a facility or organization seeking provider-based status have a reporting relationship to the main provider that is characterized by the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its departments. As evidence of this relationship, we would look to whether the facility is under the direct supervision of the provider where it is located, whether it is operated under the same monitoring and oversight as any other department of the provider, and is operated as any other department with respect to supervision and accountability. We would expect the director or individual responsible for daily operations at the facility or organization to maintain a day-to-day reporting relationship with a manager at the main provider and to be accountable to the main provider's governing body in the same manner as any department head of the provider. We also would require integration of certain

administrative functions, in particular, billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employee or group of employees would have to handle these administrative functions for both the facility or organization and the main provider, or the administrative functions for the entity and the main provider would have to be contracted out under the same contractual agreement, or be handled under different contract agreements, with the entity's contract being managed by the main provider's billing department.

In paragraph (d)(4), we are proposing that a facility or organization seeking provider-based status and the main provider share integrated clinical services, as evidenced by privileging of the professional staff of the department or entity at the main provider, and the main provider's maintenance of the same monitoring and oversight of the department or entity as of other departments. Also, the medical director of the department or entity must maintain a day-to-day reporting relationship with the chief medical officer (or equivalent) of the main provider, and be under the same supervision as any other director of the main provider. We also would expect medical staff committees or other professional committees of the main provider to be responsible for medical activities in the department or entity, including quality assurance, utilization review, and the coordination and integration of services. We also would expect medical records to be integrated into a unified retrieval system. We would expect that inpatient and outpatient services of the facility or organization and the main provider be integrated and that patients treated at the facility or organization who require further care have full access to all services of the main provider, including all inpatient or outpatient services of the main provider.

In paragraph (d)(5), we would require that the proposed department or entity and the main provider be fully financially integrated within the main provider's financial system, as evidenced by the sharing of income and expenses. The department's or entity's costs should be reported in a cost center of the provider, and the department's or entity's financial status should be incorporated into, and readily identifiable in, the main provider's trial balance.

In paragraph (d)(6), we would require that the main provider and the facility seeking status as a department of the provider be held out to the public as a single entity, so that when patients enter the department they are aware that they are entering the provider and will be billed accordingly. (This requirement would not apply to a provider-based entity that is itself a provider, such as a SNF.)

In paragraph (d)(7), we would require that the department of a provider or provider-based entity and the main provider be located on the same campus. Alternatively, the main provider and facility seeking provider-based status must demonstrate that they serve the same patient population. The department or entity and the main provider would be required to demonstrate that they serve the same patient population by submitting patient lists and/or demographic data showing that a high percentage of the patients of both come from the same geographic area, or that patients of the entity also receive a preponderance of services from the main provider. We would specify that a facility or organization is not considered to be in the ''immediate vicinity'' of the main provider if it is located in a different State than the main provider. We welcome comments as to whether an exception should be made for areas where a single metropolitan area may include two or more States.

New paragraph (e) would specifically prohibit the approval of provider-based status for any proposed department or entity that is owned by two or more providers engaged in a joint venture. Some hospitals, under joint venture arrangements, are jointly purchasing or jointly creating free-standing facilities. Although the facility or organization is operated by two or more hospitals, the dominant hospital claims the free-standing facility or organization as a department or provider-based entity. This is clearly unallowable, because the facility or organization is owned by more than one hospital, and in its own right must be considered as free-standing, subject to all of the rules and certifications that govern that type of operation.

In proposed paragraph (f), we would state that facilities or organizations operated under management contracts will be considered provider-based only if specific requirements for staff employment, administrative functions, day-to-day control of operations, and holding of the management contract by the provider itself rather than by a parent organization are met. Generally, we believe it would be difficult for any facility or organization operated under a management contract to provide all services to be able to demonstrate the degree of integration with a provider that would be needed to qualify for provider-based status. Thus, we are proposing to adopt these requirements, which are designed to ensure that we treat a facility or organization under a management contract as provider-based only if it clearly is operated by the provider, not by the management company or by a common parent organization.

In proposed paragraph (g), we would specify nine obligations of hospital outpatient departments and hospital-based entities. These obligations are spelled out in detail to help us ensure that facilities seeking recognition as hospital outpatient departments or hospital-based entities are in fact what they represent themselves as being, and are not simply the private offices of individual physicians or of physicians in group practices. The obligations are—

—In the case of hospital outpatient departments located off the main provider campus, compliance with the anti-dumping requirements in §§ 489.20 (l), (m), (q), and (r) and 489.24. If any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus and a request is made on the individual's behalf for examination or treatment of a medical condition, as described in § 489.24, the hospital must comply with the anti-dumping requirements in § 489.24. We would also revise § 489.24(b) to clarify that for purposes of the anti-dumping rules set forth in that section, hospital property means the entire main hospital campus, including the parking lot, sidewalk, and driveway, as well as any facility or organization that is located off the main hospital campus but has been determined under § 413.65 to be a department of the hospital.

—Billing of physician services in hospital outpatient departments or hospital-based entities (other than RHCs) with the correct site-of-service indicator, so that applicable site-of-service reductions to physician and practitioner payment amounts can be applied;

—In the case of hospital outpatient departments, compliance with all the terms of the provider agreement;

—Compliance by physician staff with the nondiscrimination provisions in § 489.10(b) of this chapter;

—In the case of hospital outpatient departments (other than RHCs), representation to other payers as an outpatient department of the hospital, and treatment of all patients, for billing purposes, as hospital outpatients;

—In the case of hospital outpatient departments or hospital-based entities, compliance with the payment window provisions applicable under § 412.2(c)(5) (for PPS hospitals) or § 413.40(c)(2) (for PPS-excluded hospitals);
—In the case of hospital outpatient departments or hospital-based entities (other than RHCs), notice to each beneficiary treated that he or she will be liable for coinsurance for a facility visit as well as for the physician service; and
—In the case of hospital outpatient departments, compliance with applicable Medicare hospital conditions of participation for hospitals in part 482 of this chapter.

We would also preclude any facility or organization that furnishes all services under arrangements from qualifying as provider-based. We believe the provision of services under arrangement was intended to be allowed only to a limited extent, in situations where cost-effectiveness or clinical considerations, or both, necessitate the provision of services by someone other than the provider's own staff. The ''under arrangement'' provision in section 1861(w)(1) of the Act and § 409.3 is not intended to allow a facility merely to act as a billing agent for another. We are concerned that this would be the case if all services at a facility or organization seeking provider-based status were furnished under arrangement. We believe use of arranged-for services could, if not limited, become a means of circumventing the provider-based requirements. We are proposing in paragraph (g)(10) that a facility or organization may not qualify for provider-based status if all of the services furnished at the facility are furnished under arrangements. We note that this approach is consistent with existing policy under which a hospital outpatient is expected to receive services, rather than supplies, directly from the hospital.

Proposed paragraph (h) states that if we learn of a provider that has inappropriately treated a facility or organization as provider-based, before obtaining our determination of provider-based status, we would reconsider all payments to that main provider for periods subject to reopening, investigate, and determine whether the designation was appropriate. If we find it was not provider-based, we will recover all payments in excess of those payments that should have been made in the absence of the provider-based status. As explained further below, however, recovery will not be made for any period prior to the effective date of this rule if during all of that period the management of the facility or organization made a good-faith effort to operate it as a department of a provider or provider-based entity.

In proposed paragraph (i), we would detail the application of the principles in paragraph (h) to situations involving inappropriate billing for services furnished in a physician office or other facility or organization as if they had been furnished in a hospital outpatient or other department of a provider or in a provider-based entity. Generally, when such cases of inappropriate billing are found, we will recover any overpayments as described in the preceding paragraph. Under certain circumstances, however, we will determine that the management of a facility or organization has made a good faith effort to operate it as a department of a provider or a provider-based entity and will not recover past payments. We would take this action if we determine that the requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(6) are met, all facility services were billed as if they had been furnished by a department of the main provider or a provider-based entity of the main provider, and all professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(4).

We are also proposing to add a new paragraph (j) that would allow HCFA to review past determinations. If we find that a designation was in error, and the facility or organization in question does not meet the requirements of this section, we will notify the main provider that the provider-based status will cease as of the first day of the next cost report period following notification of the redetermination.

In addition, we are proposing to add to § 413.24(d) new paragraphs (6)(i) and (6)(ii) to clarify that main providers, in completing their Medicare cost reports, may not allocate overhead costs to the provider-based or other cost centers that incur similar costs directly through management contracts or other arrangements. These changes are needed to prevent mis-allocation of management costs, which would result in excessive payment to those types of providers paid on a reasonable cost basis.

As the number of affiliation agreements among various entities has increased, there has been a noticeable shift in the way the HHAs and clinics have been managed, resulting in increased Medicare payments. Today, there are many management companies that enter into contracts with main providers to manage their provider-based entities, and the costs of these management services are being directly assigned to the department or provider-based entity receiving the service. The contracts typically call for the management company to provide the billing and accounting services, and to procure services, such as housekeeping, laundry and linen, to enable the department or provider-based entity to operate away from the campus and supervision of the main provider, even though these management companies must report to the board of the main provider. In addition to directly assigning these costs to the department or provider-based entity, the main provider, through the cost report, is still allocating overhead costs to the department or provider-based entity, even though these services are being performed through the management contract and not through the main provider. Under these circumstances, the provider could be paid three times for the same overhead cost. The first payment would be made through the PPS payment, which reflects overhead cost. The second payment would come through the cost of the management contract, and the third would come through the allocation of a share of the main provider's overhead cost to the department or provider-based entity. Our proposed changes to § 413.24 are needed to prevent this result.

To provide an administrative appeals process for entities that have been denied provider-based status, we are proposing to revise the regulations on provider appeals at § 498.3. As revised, these rules would specify that a provider seeking a determination that a facility or an organization is a department of the provider or a provider-based entity under proposed § 413.65 will be included in the definition of ''prospective provider'' for purposes of part 498, and will be afforded the same appeal rights as a prospective provider, such as a hospital or SNF, that has been found by HCFA not to qualify for participation as a provider. We believe it is in the best interest of both HCFA and health care organizations to have an explicit procedure for handling these appeals.

F. Requirements for Payment

The following discussion sets out the requirements that must be met to allow us to make payment under the outpatient PPS for various services.

1. Prerequisites for Payment for Outpatient Hospital Services and Supplies Incident to Physician Services

Medicare Part B benefits include payment for services and supplies that are furnished incident to the professional services of a physician. Medicare makes payment for services and supplies furnished in physician offices that are incident to a professional service of a physician under the provisions of the Medicare physician fee schedule (section 1848 and section 1861(s)(2)(A) of the Act; 42 CFR part 414). Payment for the ''incident to'' services furnished in physician offices is generally included within the fee for the physician services. Medicare also makes payment for hospital services and supplies that are incident to a physician service furnished to outpatients (section 1861(s)(2)(B) of the Act). Payment for ''incident to'' services furnished to hospital outpatients is *in addition to* payment for the professional services of a physician. The place where ''incident to'' services are furnished determines how Medicare pays for them.

We are proposing to add to the regulations certain prerequisites that the hospital must fulfill before it can receive Medicare payment under section 1861(s)(2)(B) of the Act for services and supplies furnished ''incident to'' physician services at a site that is off the premises of the main hospital complex. These prerequisites are intended to adapt our current policy regarding payment for ''incident to'' services furnished to hospital outpatients to address the special circumstances presented by a hospital outpatient department or clinic that is not co-located on the hospital campus or within a short distance of the hospital and that HCFA has designated is a department of the hospital or ''provider-based.''

The first prerequisite is that the office/clinic meet the responsibilities and criteria incumbent upon a provider-based entity as defined in § 413.65(g). We are proposing this requirement because the fact that a hospital owns and/or operates a clinic does not automatically make that clinic an integral, subordinate part of the hospital. If the clinic does not conform with the responsibilities and criteria at § 413.65(g), that clinic would be paid as a physician office, and Medicare payment for services furnished at that site would be made accordingly.

The second prerequisite is that the hospital seek an official determination from HCFA that the provider-based designation applies to the proposed off-site hospital outpatient department/clinic as required by § 413.65(d). The authority to determine whether or not an entity has provider-based status rests solely with HCFA. The criteria and obligations that are a prerequisite of a provider-based hospital outpatient designation are discussed earlier in this section.

Current regulations require that, in order to be paid for as ''incident to'' services, outpatient hospital services and supplies are to be furnished as an integral though incidental part of a physician service (§ 410.27(a)(1)(ii)). In addition, as a matter of policy, we require that the services and supplies be furnished on a physician's order by hospital personnel and under a physician's supervision (Intermediary Manual, section 3112.4(A)). When ''incident to'' services are furnished on hospital premises, we assume the physician supervision requirement to be met because staff physicians would be present nearby within the hospital. We also allow staff in a department of the hospital other than that of the ordering physician to supervise the services. We equate the location of the hospital outpatient department or hospital clinic within the hospital's walls, or their co-location on the same campus, with being ''on the hospital premises,'' and we assume physician supervision is always at hand. In the interests of beneficiary health and safety, we do not believe it is reasonable, safe, or appropriate to extend these assumptions to a hospital outpatient department or hospital clinic that is located off-site and that is not on the hospital premises, even if that outpatient department or clinic is accorded provider-based status. Therefore, we are proposing as the third prerequisite for a hospital to receive payment for ''incident to'' services under section 1861(s)(2)(B) of the Act, when these services are furnished at a hospital outpatient department or clinic that HCFA designates as provider-based: that the ''incident to'' services and supplies always be furnished under the direct supervision of a physician.

Unless the three prerequisites are met, we are proposing to continue to regard a clinic, even if it is owned or operated by a hospital, as a physician office or physician clinic for Medicare payment purposes. Payment for services and supplies incident to physician services that are furnished to Medicare beneficiaries at that site would only be paid in accordance with section 1848 and section 1861(s)(2)(A) of the Act, and payment would be subject to Medicare physician fee schedule payment policies and regulations (part 410; part 414).

2. Prerequisites for Payment for Hospital or Critical Access Hospital Diagnostic Services Furnished to Outpatients

Prerequisites for payment for diagnostic services furnished to hospital outpatients are addressed in § 410.28. We are proposing to add a new paragraph to the regulation that would require, at a minimum, a general level of physician supervision, and in some cases, direct or personal physician supervision, when diagnostic x-ray tests and other diagnostic tests are furnished at a hospital outpatient department or clinic that HCFA has determined meets the criteria and obligations of a provider-based entity in accordance with § 413.65. The definitions of general, direct, and personal supervision are contained in § 410.32. Although the levels of supervision defined in § 410.32 apply specifically to diagnostic x-ray and other tests that are payable under the Medicare physician fee schedule, we believe the same levels of supervision are equally relevant and reasonable and necessary to ensure that beneficiary health and safety are protected and that diagnostic x-ray and other diagnostic tests are safe and effective when they are furnished at a hospital outpatient department or clinic that HCFA has designated to be provider-based.

We are also proposing to exclude from the supervision requirement in provider-based outpatient settings the same three types of diagnostic tests that are excluded from the supervision requirement under the physician fee schedule:

- Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.
- Diagnostic tests personally furnished by a ''qualified audiologist'' as defined in section 1861(ll)(3) of the Act. These include ''audiology services'' as defined in section 1861(ll)(2) of the Act. We exclude these diagnostic tests from the physician supervision requirement because the Congress has defined these services without requiring physician supervision of their performance.
- Diagnostic psychological testing services personally performed by a qualified psychologist practicing independently of an institution, agency, or physician office as currently defined in section 2070.2 of the Medicare Carriers Manual (HCFA Pub. 14–3). These services are distinguished from services of a clinical psychologist, which are covered under section 1861(ii) of the Act, rather than section 1861(s)(3).

We are proposing to coordinate changes to the physician supervision requirements for diagnostic tests performed in outpatient settings that HCFA has designated to be provider-based with changes made to these requirements under the Medicare physician fee schedule. Refer to the final rule governing the 1998 physician fee schedule that was published in the October 31, 1997 **Federal Register** (''Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule, Other Part B Payment Policies, and Establishment of the Clinical Psychologist Fee Schedule for Calendar Year 1998'' (BPD–884–FC) (62 FR 59048)) for a full discussion. Implementing instructions for physician supervision of diagnostic tests are being developed. We note that these implementing instructions will contain revisions in the supervision levels required for many ultrasound services, stress tests, and some other services.

When diagnostic x-rays and other diagnostic tests are performed at a hospital-owned and/or operated office or clinic that is off-site and that HCFA does *not* designate as provider-based, we are proposing to pay for these services under the provisions of the Medicare physician fee schedule and the requirements of § 410.32 or under the provisions of § 410.33, if applicable.

3. Payment for Ambulatory Surgical Services

Upon implementation of the hospital outpatient PPS, Medicare payment for resource costs incurred in connection with performing ambulatory surgical procedures would be made either under the provisions of the hospital outpatient PPS; or, under the benefit established at section 1832(a)(2)(F) of the Act for facility services furnished by an approved ASC in connection with surgical procedures specified by the Secretary; or, under the physician fee schedule as established under section 1848 of the Act.

When ambulatory surgery is performed at the hospital on Medicare beneficiaries who are registered at the hospital as outpatients, Medicare would allow payment under the outpatient PPS, as explained in this proposed rule. However, Medicare would make payment under the outpatient PPS for surgical procedures performed at an off-site clinic that the hospital owns and operates and for which it submits claims only if the off-site clinic has been designated by HCFA as a department of the hospital in accordance with proposed § 413.65.

Alternatively, if the hospital-owned off-site facility is certified or accredited in accordance with ASC conditions of coverage and the requirements at part 416, Medicare would make payment for covered surgical procedures performed at the off-site facility under the ASC benefit.

However, for Medicare payment purposes, we consider an off-site office, clinic, organization, or facility that is owned and operated by a hospital but that does not meet the requirements at proposed § 413.65 or in part 416, to be a physician office or clinic, and Medicare payment for surgical procedures performed at that site would be limited to what Medicare allows for physician services furnished in connection with the surgical procedure under the Medicare physician fee schedule.

VII. MedPAC Recommendations

We reviewed the March 1998 report submitted by MedPAC to the Congress and gave its recommendations careful consideration in establishing the framework for the outpatient PPS that is the subject of this proposed rule. We responded earlier to several MedPAC recommendations that pertained directly to specific features of the outpatient PPS. In this section, we address the more general MedPAC recommendations on hospital outpatient payment policies.

Recommendation: MedPAC expresses its concern about the effects of inappropriate payment levels that could, if they are too low, restrict beneficiary access to care or prompt shifts of services for financial rather than clinical reasons, or that could, if they are too high, stimulate growth in the volume of outpatient services that is unrelated to patient needs. MedPAC states that the initial level of payment established in the BBA is a reasonable starting point for the outpatient PPS, but recommends that the Secretary monitor access to hospital outpatient services to ensure that the aggregate level of payment under the outpatient PPS is appropriate.

Response: We agree with MedPAC that monitoring service patterns not only in hospital outpatient departments but across all ambulatory settings subsequent to implementation of the outpatient PPS is essential in order to detect sudden changes and to identify variant trends in where services are being furnished to Medicare beneficiaries. As is MedPAC, we too are aware of how vividly any differences in payment for services furnished in different ambulatory settings will be revealed once the outpatient PPS is implemented, and we expect that these differences will, not surprisingly, precipitate shifts in services from one setting to another. It is the recognition of this likely outcome that makes it all the more urgent that we resolve the dilemma posed by two conflicting policy determinations raised by MedPAC: whether to set Medicare payments to reflect the cost of providing a service regardless of where the service is furnished or whether to set Medicare payments to acknowledge that the site where a service is furnished could affect the cost of furnishing the service. As we discuss below, we clearly are inclined toward a position that Medicare should determine payment on the basis of the service that is furnished rather on the setting where that service is furnished, but there are many factors still to be considered before making such a determination final. In the meantime, we believe that the adjustments provided for under the outpatient PPS will contribute to ensuring that Medicare is paying adequately for services, especially in areas where a hospital is the only provider of services to which beneficiaries have access. We particularly welcome comments and suggestions regarding methods by which we can enhance our monitoring of service delivery patterns to ensure that the outpatient PPS is not adversely affecting beneficiary access to hospital outpatient care in accordance with MedPAC's recommendation. We agree with MedPAC's concern that payment levels under the outpatient PPS be sufficient to support the provision of services, especially in areas where a hospital is the only provider of such services, but that payment levels under the outpatient PPS not exceed payments for the same services at other ambulatory sites to such a degree as to cause shifts in where services are provided for financial rather than clinical reasons.

Recommendation: MedPAC recommends that HCFA continue to investigate service classification systems that could be applied consistently to all ambulatory care settings. In its 1998 report to Congress, MedPAC expresses concern about the impact on service delivery of paying different amounts for the same service based on where the service is furnished. MedPAC appears to favor Medicare ambulatory care payment systems that are standardized across hospital outpatient, physician office, and ASC settings. MedPAC equates ''standardized'' with ''policies that are comparable for the same service, regardless of setting,'' (p. 83) and ''* * * consistency of payment across all ambulatory settings'' (p. 84).

Response: In principle, we agree that establishing Medicare payment

uniformity across ambulatory care settings is important. We have, to the extent permitted by the statute, incorporated into the outpatient PPS elements of Medicare payment policy for ASCs and for physician services.

Upon implementation of the outpatient PPS, the same unit of payment (HCPCS codes and descriptors) will be used for all three settings. Packaging under the outpatient PPS parallels that for ASCs. At least initially, volume control under the outpatient PPS parallels that which is applied to physician services. The policy for discounting multiple procedures will be comparable under the outpatient PPS, the ASC benefit, and the physician fee schedule. APC groups will be used to set rates for ASC payments and for hospital outpatient surgical services, and we propose to pay for the same surgical procedures in both settings. Notwithstanding these similarities, payment rates for most procedures will not be the same for ASCs and under the outpatient PPS. We use different data and methods to set rates for ASC services, for physician services, and for hospital outpatient services. The latter is attributable primarily to the fact that the statute sets forth criteria that are to be considered when setting payment mechanisms that are specific to each site of service.

Several fundamental issues must be addressed before we achieve the goal of making consistent payment for the same service across all ambulatory sites of service. First, consensus must be reached on what constitutes ''consistent payment.'' Even MedPAC equivocates on this point, noting that while it believes that ''Medicare's payment should reflect the cost of efficiently providing a service, regardless of where it is delivered * * * (b)ecause of access or quality concerns * * * it may be appropriate to continue to pay different amounts for the same service, depending on the setting in which it is furnished.'' Does ''consistent'' or ''comparable'' payment mean the *same* payment for a service regardless of setting? Or would consistency be achieved by using the same group weights for hospital outpatient and ASC payment rates even though we used site-specific conversion factors, resulting in different payment rates? Should we use ASC groups as the basis for setting payments for physician services? Is there a single index that is appropriate to standardize variations in costs attributable solely to geographical differences? And which legislative changes would be required to standardize payment for services across ambulatory settings? These are but a few of the issues and options that we and stakeholders across the spectrum of ambulatory care must thoroughly examine and analyze as we move towards standardizing payments across ambulatory sites of service. We solicit comments on this issue, on options to be considered in restructuring Medicare payment provisions towards the goal of establishing payment uniformity across ambulatory sites, and on strategies for achieving consensus on the definition of both goals and the means of attaining them.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the provisions summarized below that contain information collection requirements:

Section 413.65 Requirements for a Determination That a Facility or an Organization is a Department of a Provider or a Provider-Based Entity

Section 413.65(c)(1) and (c)(2) states that a main provider that acquires a facility or organization for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital outpatient department or clinic, must report its acquisition of the facility or organization to HCFA and must furnish all information needed for a determination as to whether the facility or organization meets the requirements in paragraph (d) of this section for provider-based status. This requirement applies, however, only if the facility or organization is located off the campus of the provider, or inclusion of the costs of the facility or organization on the provider's cost report would increase the total costs on the report by at least 5 percent. Furthermore, a main provider that has had one or more entities considered provider-based also must report to HCFA any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization.

The burden associated with this requirement is the time for the main provider to report its acquisition to HCFA, furnish all information needed for a determination, report to HCFA any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization. It is estimated that 105 main providers will take 10 hours for a total of 1,050 hours.

Section 419.42 Hospital Election To Reduce Copayment

Section 419.42(b) and (c) states that a hospital must notify its fiscal intermediary of its election to reduce copayments no later than 90 days prior to the start of the calendar year. The hospital's election must be properly documented. It must specifically identify the ambulatory payment classification to which it applies and the copayment level (within the limits identified below) that the hospital has selected for each group.

The burden associated with these requirements is the time it takes a hospital to compile, review, and analyze data for both revenues and copayments; prepare and present the data to the hospital board; make a business decision as to whether the hospital would elect to reduce copayments; and then notify its fiscal intermediary of its election. A hospital would notify its fiscal intermediary of its election to reduce copayments only if there were other providers, in close proximity, that would attract a majority of the hospital's business if they did not reduce their copayments. Since hospitals do not want to lose money by absorbing copayments, we anticipate that this requirement will affect 750 hospitals and take them 10 hours each for a total of 7,500 hours.

Section 419.42(e) states that the hospital may advertise and otherwise disseminate information concerning the reduced level(s) of coinsurance that it has elected.

The burden associated with this requirement is the time for the hospital to disseminate information concerning its coinsurance election. It is estimated that 750 hospitals will each take 10 hours annually to disseminate this information via newsletters and information sessions at senior citizen centers for a total of 7,500 hours.

While the information collection requirements listed below are subject to the Paperwork Reduction Act, the burden associated with these requirements is captured under § 413.65(c)(1) and (c)(2).

Section 413.65(b)(2) states that a provider or a facility or organization must contact HCFA and the facility or organization must be determined by HCFA to be provider-based before the main provider begins billing for services of the facility or organization as if they were furnished by a department of the provider-based entity, or before it includes costs of those services on its cost report.

Section 413.65(d)(7)(i) requires that the facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria, and demonstrates that it serves the same patient population as the main provider, either by submitting records such as common patient lists and/or demographic data showing that a high percentage of patients of both the main provider and the applicant entity come from the same geographic area, or by submitting data substantiating that the patients served by the entity also receive services from the main provider (for example, the patients of an RHC receive inpatient hospital services from the main provider).

While the information collection requirements listed below are subject to the Paperwork Reduction Act, we believe the burden associated with these requirements is not subject to the Act, as defined by 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

Section 413.65(g)(7) states that when a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity, the hospital has a duty to notify the beneficiary, prior to the delivery of services, of the beneficiary's potential financial liability (that is, a coinsurance liability for a facility visit as well as for the physician service).

We believe the information collection requirement below is exempt from the Paperwork Reduction Act, as defined by 5 CFR 1320.4(a)(2), since this activity is pursuant to the conduct of an investigation or audit against specific individuals or entities.

Section 413.65(i)(1) states that if HCFA determines that a provider has been inappropriately billing Medicare for services furnished in a physician office or other facility or organization as if they had been furnished in a hospital outpatient department or other department of a provider or in a provider-based entity, HCFA stops all payments to the provider for outpatient services until the provider can demonstrate which payments are proper.

The table below indicates the annual number of responses for each regulation section in this proposed rule containing information collection requirements, the average burden per response in minutes or hours, and the total annual burden hours.

ESTIMATED ANNUAL BURDEN

CFR section	Responses	Average burden per response (hours)	Annual burden hours
413.65(c)(1) and (c)(2)	105	10	1,050
419.42(b) and (d)	750	10	7,500
419.42(f)	750	10	7,500
Total			16,050

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Louis Blank HCFA–1005–P, Fax number: (410) 786–1415 and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Allison Herron Eydt, HCFA Desk Officer, Fax numbers: (202) 395–6974 or (202) 395–5167.

IX. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

X. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Because the projected savings resulting from this proposed rule are

expected to exceed $100 million, it is considered a major rule.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This proposed rule does not mandate any requirements for State, local, or tribal governments. However, our estimations indicate that the loss of income to the private sector as a result of this rule should exceed $300 million total to all hospitals.

We generally prepare a regulatory flexibility analysis that is consistent with the RFA (5 U.S.C. 601 through 612), unless we certify that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospitals to be small entities.

Also, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Public Law 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the proposed prospective payment system, we classify these hospitals as urban hospitals.

B. Estimated Impact on Medicare Program

According to HCFA's Office of the Actuary, the benefit impacts of the hospital outpatient PPS (including elimination of the formula-driven overpayment (FDO) effective as of October 1, 1997, extension of the 10 percent reduction in payments for hospital outpatient capital cost and the 5.8 percent reduction for outpatient services paid on a cost basis through CY 1999, and the implementation of a PPS for hospital outpatient services on January 1, 1999 would be as follows:

Fiscal year	Impact ($ millions)
1998	−940
1999	−1650
2000	−1330
2001	−1070
2002	−990
2003	−680

The use of the national median of the charges for PPS services to establish the unadjusted copayment amount would have resulted in the beneficiaries paying 6.9 percent less in coinsurance payments in 1999 than what they would have been expected to pay otherwise. It was assumed that there would have been a behavioral offset by the hospitals of 10 percent of the coinsurance reduction. It was assumed that 45 percent of this offset would apply to the services subject to the PPS and, therefore, would have been included in setting the 1999 conversion factor. The remaining 55 percent of the offset would be reflected in expenditures for non-PPS services with both the beneficiary and Medicare absorbing this impact. With the delay in implementation of the outpatient PPS, the behavioral offset will not occur in 1999, and, therefore, there will be slightly higher program savings.

C. Objectives

The primary objective of the proposed prospective payment system is to simplify the payment system while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs. In addition, we share national goals of deficit reduction and restraints on government spending in general.

We believe the proposed changes would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of this payment system are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes, on various hospital groups. We use the best data available; in addition, we do not make adjustments for future changes in such variables as volume and intensity. As we have done in previous proposed rules, we are soliciting comments and information about the anticipated effects of these changes on hospitals and our methodology for estimating them.

E. Hospitals Included in and Excluded From the Prospective Payment System

The outpatient prospective payment system encompasses nearly all hospitals that participate in the Medicare program. However, those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the PPS. Critical access hospitals (CAHs) are also excluded and are paid at cost under section 1834(g).

F. Quantitative Impact Analysis of the Proposed Policy Changes Under the Prospective Payment System for Operating Costs and Capital Costs

Basis and Methodology of Estimates

The data used in developing the quantitative analyses presented below are taken from the CY 1996 cost and charge data and the most current provider-specific file that is used for payment purposes. Our analysis has several qualifications. First, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases, there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available source overall. For individual hospitals, however, some miscategorizations are possible.

Using CY 1996 cost and charge data, we simulated payments using the current and proposed payment methodologies. We used both single and multiple bills to calculate current and proposed Medicare and beneficiary hospital outpatient payment amounts. Both current and proposed payment estimates include operating and capital costs. The exempted Maryland hospitals were excluded from the simulations; however, we included the 10 cancer hospitals that will be paid under the proposed system.

We also trimmed outlier hospitals from the impact analysis because we had indications that hospitals with extreme unit costs would not allow us to assess the impacts among the various classes of hospitals accurately. First, we identified all the outlier hospitals by using an edit of three standard deviations from the mean of the logged unit costs. Trimming the data in this manner ensures that only the hospitals with extremely high and low costs are eliminated from the impacts. In doing this, we removed 83 hospitals of which 32 hospitals had extremely low unit costs and 51 hospitals had extremely

high unit costs. We conducted a thorough analysis of these hospitals to ensure that we did not remove any particular type of hospital (for example, teaching hospitals) that would further harm the integrity of the data. We speculate many of these hospitals are not coding accurately, and we will continue to perform further analysis in this area after implementation of the new APC system.

After removing the 54 exempted Maryland hospitals, outlier hospitals, and hospitals for which we could not identify payment variables, we included 5,419 hospitals in our analysis. The impact analysis focuses on this set of hospitals. The table below demonstrates the results of our analysis. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The first column represents the number of hospitals in each category. The second column is the hospitals' Medicare outpatient payments as a percentage of the hospitals' total Medicare payment. The third column shows the percentage change in Medicare outpatient payments comparing the current and proposed payment systems. The fourth column shows the change in total Medicare payments, resulting from implementing the PPS for outpatient services.

The top row of the table shows the overall impact on the 5,419 hospitals included in the analysis. We included as much of the data as possible to the extent that we were able to capture all the provider information necessary to determine payment. Further, our estimates include the same set of services for both current and proposed APC payments so that we could determine the impact as accurately as possible. Since payment under the proposed APC system can only be determined if bills are accurately coded, the data upon which the impacts were developed do not reflect all CY 1996 hospital outpatient services, but only those that were coded using valid HCPCS.

The second row identifies the hospitals in our analysis with the exception of psychiatric, long-term care, children, and rehabilitation hospitals, which account for 4,864 hospitals.

The next four rows of the table contain hospitals categorized according to their geographic location (all urban, which is further divided into large urban and other urban, or rural). There are 2,677 hospitals located in urban areas (MSAs or NECMAs) included in our analysis. Among these, there are 1,516 hospitals located in large urban areas (populations over 1 million), and 1,161 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 2,187 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The next category includes the volume of outpatient services, also shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have residency programs (teaching hospitals that receive an indirect medical education (IME) adjustment), receive disproportionate share hospital (DSH) payments, or some combination of these two adjustments. There are 3,847 non-teaching hospitals in our analysis, 766 teaching hospitals with fewer than 100 residents, and 250 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status. The next category groups hospitals considered urban after geographic reclassification, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither. The next five rows examine the impacts of the proposed changes on rural hospitals by special payment groups (rural referral centers (RRCs), sole community hospitals/essential access community hospitals (SCHs/EACHs), Medicare dependent hospitals (MDHs), and SCHs and RRCs), as well as rural hospitals not receiving a special payment designation. The RRCs (168), SCH/EACHs (625), MDHs (365), and SCH and RRCs (55) shown here were not reclassified for purposes of the standardized amount.

The next grouping is based on type of ownership. These data are taken primarily from the FY 1995 Medicare cost report files, if available (otherwise, FY 1994 data are used).

The next groupings are the specialty hospitals. The first set includes the categorizations of eye and ear hospitals and trauma hospitals (hospitals having a level one trauma center) and cancer hospitals. The final groupings are the TEFRA hospitals, specifically rehabilitation, psychiatric, long-term care, and children hospitals.

G. Estimated Impact of the New APC System

Column 3 compares our estimate of payments, incorporating statutory and policy changes reflected in this proposed rule for CY 1996, to our estimate of payments in CY 1996 under the current payment system. Percent differences between current and proposed payment reflect the combined impact of a proportionally equal reduction in payments due to the calculation of the conversion factor and distributional differences attributable to variation in cost and charge structures among hospitals. The methodology described in section 1833(t)(3)(C) of the Act outlining the calculation of the conversion factor reduces payment to hospitals overall by 3.8 percent relative to current law. As noted, section 1833(t)(3)(C) of the Act requires us to set the conversion factor so that total 1999 payments to hospitals under the proposed PPS system equal Medicare payment amounts as calculated under the current payment system plus beneficiary copayments as calculated under the proposed system (20 percent of the APC median charge or, at minimum, 20 percent of the APC rate). The 3.8 percent loss implies that the difference between the median and charges higher than the median was proportionally larger than the difference between the median and charges lower than the median. Because this reduction is incorporated into the conversion factor, the 3.8 percent is distributed among hospitals proportional to their total payments. After removing the effect of the conversion factor calculation on total payments, the remaining percent differences demonstrate the redistribution of payments among hospitals and can be attributed to variation in both costs and charge structures. Variation in costs among hospitals results in differences between current and proposed Medicare payments, and variation in charge structures results in differences between current and proposed beneficiary copayment.

Redistributions may also occur as a result of current payment methods. Total Medicare outpatient payments are less than reported total costs because (in addition to the 5.8 and 10 percent reductions for operating and capital costs) the blended payment methods applicable to many surgical and diagnostic services often result in payments that are less than reported costs. Other services such as medical visits, chemotherapy services, partial hospitalization services, and non-ASC approved surgeries are paid based on hospital costs. The new system redistributes the current total Medicare payments, based in part on cost-based payments and in part on blended

payment amounts, across all services. Hospitals, in the aggregate, will receive proportionately less for services that are currently paid based on costs and more for services that had been paid under blended payment methods.

The impact on TEFRA hospitals is shown separately at the end of the table; however, these hospitals were not included in determining the impact on any of the other categories (for example, geographic location, bed size, volume, etc.). These hospitals demonstrated a very low service mix, but an average unit cost that is only somewhat smaller than the national average. We believe that billing practices may account for this phenomenon. Some TEFRA hospitals appear to under-code HCPCS and units. This may be because correct coding is not required for payment or because they bill an all-inclusive rate. Undercoding or billing an all-inclusive rate could account for their low volume, low service mix, and almost average cost per unit. We expect that once these hospitals begin to code HCPCS according to the new payment system, new payments will better reflect current payments.

In general, differences among hospital classifications for short-term acute care hospitals were relatively small. That is, payments under the proposed outpatient system were within a few percentage points of payments made under current law. The following discussion highlights some of the variation in payments among hospital classifications.

Based on comparing current and proposed payment estimates, minor teaching hospitals lose 1.8 percent, while major teaching hospitals experience a reduction of 9.4 percent. Non-teaching hospitals experience a decrease of 3.1 percent. However, major teaching hospitals gain less of their total Medicare income (9.2 percent) from outpatient services than the national average (10 percent). This results in a less than 1 percent loss in their total Medicare income.

Hospitals with a high percentage of low income patients (disproportionate share patient percentage ≤ 0.35) appear to experience payment reductions of 6.8 percent relative to current law. These hospitals have lower than average volume, and, like major teaching hospitals, they receive a smaller than average percent of their Medicare income from outpatient services.

Rural hospitals would lose about 5.2 percent and large urban hospitals would lose about 5.0 percent under the new system while other urban hospitals would lose 0.9 percent. These small differences illustrate fairly equitable payment among these geographical settings. However, rural hospitals get a greater percentage of their Medicare income (14.7 percent) from outpatient services compared to the national average of 10 percent.

Low-volume hospitals appear to lose a large percentage of their payments under the new payment system (17 percent for rural and 15.6 percent for urban hospitals with less than 5,000 units of service). We believe several factors are contributing to this outcome, including undercoding, lack of economies of scale, and underpayment due to the reliance on the median instead of the geometric mean in the calculation of APC weights. The majority of these hospitals (about 75 percent) are rural. These hospitals also have a service mix (1.03) lower than the national average (1.45) and higher than average hospital cost per unit standardized for service mix. For these small hospitals, some of the higher standardized unit costs could be attributed to economies of scale. These low-volume rural hospitals also receive a greater percentage of their Medicare income (18.2 percent) from outpatient services than the average. SCHs and MDHs comprise about 60 percent of these low-volume rural hospitals.

As discussed previously in section V.I, the Adjustments section, we are particularly concerned about the potential impact on the approximately 60 percent of low-volume rural hospitals that are sole community hospitals or Medicare-dependent hospitals. As previously discussed, one option would be to phase-in the outpatient PPS for low-volume Medicare-dependent and sole community hospitals by paying a portion of the payment based on PPS rates and a portion based on the current payment system. For example, payment could be based on 75 percent of payments under the current system and 25 percent on PPS rates in the first year, 50 percent current system payments and 50 percent PPS rates in the second year, 25 percent current system payments and 75 percent PPS rates in the third year, and completely on PPS rates in subsequent years. If such an approach were adopted, the impact on Medicare outpatient payment for these hospitals would be as follows:

ESTIMATED IMPACT OF A TRANSITION POLICY ON MEDICARE OUTPATIENT PAYMENTS FOR MEDICARE-DEPENDENT AND SOLE COMMUNITY HOSPITALS

[In percent]

	Year 1	Year 2	Year 3	Year 4
MDH	−2.1	−4.3	−6.4	−8.5
SCH	−1.7	−3.3	−5.0	−6.7
SCH/RRC	−0.5	−1.0	−1.6	−2.1

Another option discussed earlier in the adjustments section would phase-in outpatient PPS if a low-volume sole community or Medicare-dependent hospital has a negative Medicare margin for outpatient services. For example, payment could be based on the amount payable under outpatient PPS plus a percentage of the difference between those amounts and the amounts payable under the current system. The percentage of the difference that would be payable could phase down, for example, 75 percent in the first year, 50 percent in the second year, 25 percent in the third year, and no additional payment in subsequent years. We solicit comments on these and other alternatives we could consider.

As noted above, rural hospitals lose a larger percent of their payments than urban hospitals. Among the census divisions, rural New England hospitals experience the largest negative payment impact of 13.6 percent. This could be attributed to higher non-labor costs in New England. West North Central hospitals also would experience a 7.7 percent payment loss.

Urban census division breakouts reveal that Middle Atlantic urban hospitals lose 11.3 percent of payments while the other urban census regions gain or lose modestly.

Hospitals located in Puerto Rico gain because of the change in the beneficiary copayment. Previously these hospitals received 20 percent of their charges from the beneficiary, whereas under the

new PPS they would receive 20 percent of the APC median charge or, at minimum, they would receive 20 percent of the payment rate. Hospitals in Puerto Rico gain under the new proposed system because 20 percent of their charges are lower than 20 percent of the APC median charges or 20 percent of the rates.

Among special categories of rural hospitals, MDHs and SCHs/EACHs would experience decreases of 8.5 and 6.7 percent, respectively. Some of this decrease may be attributed to the impact on low-volume rural hospitals.

Cancer hospitals experience a 29.2 percent loss. Several factors may contribute to this loss. Under-coding could be a factor contributing to the percentage loss. In addition, the current requirements for batch billing of services such as chemotherapy and radiation therapy and the fact that we used only single procedure bills to calculate group weights may also have contributed to the impact on these hospitals. Further analysis will be conducted to determine if current coding practices explain the negative impact. We will be verifying the accuracy of the rates for these types of procedures. Specifically, the APC weights were calculated using single bill procedures. Using single bill procedures to compute a weight for services which are not typically billed as a single procedure could result in rates that are not accurate for these services. We will verify the accuracy of the rates for these types of procedures by analyzing the costs from the multiple bills. If further analysis reveals that cancer hospitals would be unduly harmed because of the new outpatient PPS, we will consider whether an adjustment or perhaps a transition period is needed to moderate the impact. By statute, any adjustment would have to be budget neutral. Until further analysis can be conducted we are not proposing an adjustment for cancer hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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